AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

# FEDERAL REGISTER

Vol. 80 Friday,

No. 94 May 15, 2015

Pages 27851–28152

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing 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.ofr.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 at *www.fdsys.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** 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 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

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 Publishing 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: 80 FR 12345.

**Postmaster:** Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing 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:**

Assistance with Federal agency subscriptions:

| | |
|---|---|
| Email | *FRSubscriptions@nara.gov* |
| Phone | **202–741–6000** |

Printed on recycled paper.

# Contents

**Federal Register**

Vol. 80, No. 94

Friday, May 15, 2015

**Agriculture Department**
*See* Food and Nutrition Service
*See* Rural Business-Cooperative Service
*See* Rural Housing Service

**Census Bureau**
RULES
Foreign Trade Regulations:
Reinstatement of Exemptions Related to Temporary Exports, Carnets, and Shipments under a Temporary Import Bond, 27853–27854

**Centers for Medicare & Medicaid Services**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 27971–27972

**Civil Rights Commission**
NOTICES
Meetings:
Michigan Advisory Committee, 27895–27896

**Coast Guard**
RULES
Special Local Regulations:
Annual Marine Events on the Colorado River, Between Davis Dam and Headgate Dam Within the San Diego Captain of the Port Zone, 27858–27859
NOTICES
Certificate of Alternative Compliance for the P/V LUCIA, 1257462, 27982–27983

**Commerce Department**
*See* Census Bureau
*See* Economic Development Administration
*See* Foreign-Trade Zones Board
*See* National Oceanic and Atmospheric Administration
*See* National Telecommunications and Information Administration

**Committee for Purchase From People Who Are Blind or Severely Disabled**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Initial Certification, 27930
Procurement List; Additions and Deletions, 27929–27930

**Commodity Futures Trading Commission**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Customer Clearing Documentation and Timing of Acceptance for Clearing, 27930–27932

**Defense Department**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 27938–27939
Arms Sales, 27932–27941

**Drug Enforcement Administration**
RULES
Schedules of Controlled Substances:
UR–144, XLR11, and AKB48; Extension of Temporary Placement in Schedule I, 27854–27856
NOTICES
Importer of Controlled Substances Registration:
Cambrex Charles City, 28009–28010

**Economic Development Administration**
NOTICES
Petitions:
Trade Adjustment Assistance, 27896

**Education Department**
PROPOSED RULES
Priorities, Requirements, Definitions, and Selection Criteria:
Demonstration and Training Program; Career Pathways for Individuals with Disabilities, 27874–27878
Vocational Rehabilitation Technical Assistance Center—Youth with Disabilities, 27868–27873
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Health Education Assistance Loan Program; Forms, 27941

**Energy Department**
*See* Federal Energy Regulatory Commission
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board, Paducah, 27941–27942

**Environmental Protection Agency**
RULES
National Oil and Hazardous Substances Pollution Contingency Plans:
National Priorities List Deletion of the Burrows Sanitation Superfund Site, 27859–27862
PROPOSED RULES
National Oil and Hazardous Substances Pollution Contingency Plans:
National Priorities List Deletion of the Burrows Sanitation Superfund Site, 27883–27884
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Data Reporting Requirements for State and Local Vehicle Emission Inspection and Maintenance Programs, 27949–27950
Environmental Impact Statements; Availability, etc.; Weekly Receipts, 27950–27951

**Export-Import Bank**
NOTICES
Applications for Long-Term Loans or Financial Guarantees in Excess of $100 million, 27951–27952

**Federal Aviation Administration**
RULES
Noise, Fuel Burn, and Emissions Modeling Using the Aviation Environmental Design Tool, 27853

**Federal Communications Commission**
RULES
Low Power Television and TV Translator Stations:
Suspension of Digital Transition Date, 27862–27863
NOTICES
Meetings:
Consumer Advisory Committee, 27952–27953

**Federal Emergency Management Agency**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Direct Housing Program Forms, 27994–27995
Manufactured Housing Operations Forms, 27994
Flood Hazard Determinations, 27985–27986, 27988–27990
Flood Hazard Determinations; Changes, 27987–27988, 27990–27994
Major Disaster Declarations:
Kentucky; Amendment No. 1, 27990
Tennessee; Amendment No. 2, 27985
Major Disasters and Related Determinations:
Kentucky, 27984–27985

**Federal Energy Regulatory Commission**
NOTICES
Applications:
Tri-Dam Project, 27942–27943
Authorizations for Continued Project Operations:
Village of Morrisville, VT, 27945–27946
Combined Filings, 27943–27944, 27946–27947
Complaints:
New York Public Service Commission, et al. v. New York Independent System Operator, Inc., 27942
Filings:
Entergy Gulf States Louisiana, LLC, et al., 27945
Huskilson, Christopher G., et al., 27948
Oncor Electric Delivery Co., LLC, 27945
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Blue Cube Operations, LLC, 27947–27948
Greenleaf Power Management, LLC, 27948
License Applications:
Warmsprings Irrigation District; Withdrawal, 27944
Petitions for Rate Approvals:
Enterprise Texas Pipeline, LLC; Staff Protest, 27944–27945
Preliminary Permit Applications Accepted for Filing and Soliciting Comments, Motions to Intervene, and Competing Applications:
Spartanburg Water System, 27948–27949
Preliminary Permit Applications:
Mid-Atlantic Hydro, LLC, 27949
Requests under Blanket Authorization:
Tallgrass Interstate Gas Transmission, LLC, 27947

**Federal Highway Administration**
NOTICES
Federal Agency Actions:
Colorado Highways, 28041–28043

**Federal Reserve System**
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 27953–27954

**Federal Trade Commission**
NOTICES
Consent Orders:
Holcim, Ltd. and Lafarge S.A., 27961–27970
ZF Friedrichshafen AG and TRW Automotive Holdings Corp., 27954–27961

**Food and Drug Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery, 27975
Guidance for Industry and Staff:
Investigational New Drug Applications by Sponsor-Investigators, 27972–27973
Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 27973–27975
Meetings:
Food and Drug Administration–American Urological Association–Society of Urologic Oncology Workshop on Partial Gland Ablation for Prostate Cancer, 27973

**Food and Nutrition Service**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Supplemental Nutrition Assistance Program Forms — Applications, Periodic Reporting and Notices, 27885–27886

**Foreign-Trade Zones Board**
NOTICES
Approvals of Subzone Status:
Spectro Coating Corporation d/b/a Claremont Flock, LLC, Leominster, MA, 27896–27897
Production Activities:
MHI Compressor International Corp., Foreign-Trade Zone 84, Houston, TX, 27897
Reorganizations under Alternative Site Frameworks:
Foreign-Trade Zone 49, Newark/Elizabeth, NJ, 27897

**General Services Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Acquisition Regulation; Environmental Conservation, Occupational Safety, and Drug-Free Workplace, 27970–27971

**Health and Human Services Department**
*See* Centers for Medicare & Medicaid Services
*See* Food and Drug Administration
*See* National Institutes of Health
*See* Substance Abuse and Mental Health Services Administration
RULES
Specifications for Medical Examinations of Coal Miners; CFR Correction, 27862
NOTICES
Meetings:
U.S. National Authority for the World Health Organization Global Code of Practice on the International Recruitment of Health Personnel, 27975

**Homeland Security Department**
*See* Coast Guard
*See* Federal Emergency Management Agency
*See* U.S. Customs and Border Protection

**Housing and Urban Development Department**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals
Assessment of Technology Needs in HUD-Subsidized Housing, 27996–27997
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Federal Housing Administration Insured Mortgages, 27998–27999
Federal Property Suitable as Facilities to Assist the Homeless, 27997–27998
Manufacturer Notification and Correction Plan; Extension of Time for Completion, 27995–27996

**Indian Affairs Bureau**
NOTICES
Environmental Impact Statements; Availability, etc.:
Aiya Solar Project, Clark County, NV, 28001–28002
Tribal Education Department Grant Program, 27999–28000

**Interior Department**
*See* Indian Affairs Bureau
*See* Land Management Bureau
*See* Office of Natural Resources Revenue

**International Trade Commission**
NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
Sugar from Mexico, 28009

**Justice Department**
*See* Drug Enforcement Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Community Oriented Policing Services Extension Request Form, 28010–28011
Consent Decrees under the Clean Air Act, Clean Water Act, and Emergency Planning and Community Right to Know Act, 28011
Proposed Consent Decree Under the Clean Water Act, 28010

**Labor Department**
*See* Labor Statistics Bureau
*See* Mine Safety and Health Administration

**Labor Statistics Bureau**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 28011–28013

**Land Management Bureau**
NOTICES
Coal Lease Sales:
Utah, 28002–28003
Temporary Closures of Public Lands:
Washoe County, NV, 28002

**Maritime Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement, 28044
Requests for Administrative Waivers of the Coastwise Trade Laws:
Vessel HULA GIRL, 28043–28044
Vessel LIMITLESS, 28046
Vessel SEA FOX, 28045–28046
Vessel WATERBOUND, 28043
Requests for Administrative Waivers of the Coastwise Trade Laws:
Vessel ZUIMACO, 28044–28045

**Mine Safety and Health Administration**
NOTICES
Petitions for Modification:
Application of Existing Mandatory Safety Standards, 28013–28014

**National Aeronautics and Space Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 28014–28015
Centennial Challenges 3D Printed Habitat Challenge, 28014

**National Institutes of Health**
NOTICES
Meetings:
Center for Scientific Review, 27975–27980
Eunice Kennedy Shriver National Institute of Child Health and Human Development, 27978, 27981
National Cancer Institute, 27979, 27981–27982
National Heart, Lung, and Blood Institute, 27978
National Institute of Allergy and Infectious Diseases, 27978, 27980–27981
National Institute of Dental and Craniofacial Research, 27981
National Institute on Alcohol Abuse and Alcoholism, 27979

**National Oceanic and Atmospheric Administration**
RULES
Atlantic Highly Migratory Species:
Atlantic Bluefin Tuna Fisheries, 27863–27867
NOTICES
Applications:
National Marine Sanctuary Advisory Councils, 27926–27927
Endangered and Threatened Species:
Cook Inlet Beluga Whale; Draft Recovery Plan, 27925–27926
Funding Availability:
Coastal Ecosystem Resiliency Grants Program, 27898–27901
Meetings:
Mid-Atlantic Fishery Management Council; Fisheries of the Northeastern United States, 27897–27898
New England Fishery Management Council, 27927–27928
Permits:
Marine Mammals; File No. 19526, 27928
Takes of Marine Mammals:
Shallow Geohazard Survey; Beaufort Sea, Alaska, 27901–27925

**National Telecommunications and Information Administration**

NOTICES
Meetings:
First Responder Network Authority Board, 27928–27929

**Office of Natural Resources Revenue**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Royalty and Production Reporting, 28003–28007
United States Extractive Industries Transparency Initiative, 28007–28009

**Pension Benefit Guaranty Corporation**
RULES
Benefits Payable in Terminated Single-Employer Plans:
Interest Assumptions for Paying Benefits, 27857–27858

**Postal Regulatory Commission**
NOTICES
Changes in Postal Prices, 28015–28016
Meetings; Sunshine Act, 28015

**Presidential Documents**
ADMINISTRATIVE ORDERS
Yemen: Continuation of National Emergency (Notice of May 13, 2015), 27851

**Railroad Retirement Board**
NOTICES
Privacy Act; Systems of Records, 28016–28021

**Rural Business-Cooperative Service**
NOTICES
Inviting Applications for Value-Added Producer Grants, 27886–27887

**Rural Housing Service**
NOTICES
Applications:
Rural Community Development Initiative, 27887–27895

**Securities and Exchange Commission**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 28021, 28036–28037
Applications:
Business Development Corporation of America, et al., 28027–28031
The MainStay Funds, et al., 28031–28035
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Board Options Exchange, Inc., 28021–28027
ICE Clear Europe, Ltd., 28035–28036

**Small Business Administration**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 28037–28039
Disaster Declarations:
Florida, 28039
Tennessee; Amendment 2, 28039
SBIR/STTR Logo Design Competition Announcement; Correction, 28037

**State Department**
RULES
Passports: Official Passports for Officials or Employees of State, Local, Tribal or Territorial Governments Traveling Abroad and Carrying Out Official Duties in Support of the U.S. Government, 27856–27857

**Substance Abuse and Mental Health Services Administration**
NOTICES
Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid, 28054–28101
Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine, 28101–28151

**Surface Transportation Board**
NOTICES
Acquisition Exemptions; Lines of CSX Transportation, Inc.:
Eighteen Thirty Group, LLC, 28046
Lease Amendments and Operation Exemptions:
San Joaquin Valley Railroad Co.; BNSF Railway Co., 28047
Operation Exemptions:
Georges Creek Railway, LLC; Lines of CSX Transportation, Inc., 28047

**Susquehanna River Basin Commission**
NOTICES
Projects Approved for Consumptive Uses of Water, 28039–28041

**Transportation Department**
*See* Federal Aviation Administration
*See* Federal Highway Administration
*See* Maritime Administration
*See* Surface Transportation Board

**Treasury Department**
*See* United States Mint

**U.S. Customs and Border Protection**
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals
Guarantee of Payment, 27983–27984
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Entry and Manifest of Merchandise Free of Duty, Carrier's Certificate and Release, 27983

**United States Mint**
NOTICES
Meetings:
Citizens Coinage Advisory Committee, 28048–28049
Requests for Nominations:
Citizens Coinage Advisory Committee, 28048

**Veterans Affairs Department**
PROPOSED RULES
Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans:
Covered Birth Defects and Spina Bifida, 27878–27883
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Expanded Access to Non-VA Care Through the Veterans Choice Program, 28049–28050
Notice of Lapse — Government Life Insurance, 28050–28051
Supplier Perception Survey, 28050

## Separate Parts In This Issue

### Part II

Health and Human Services Department, Substance Abuse and Mental Health Services Administration, 28054–28151

## 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.

**3 CFR**
**Administrative Orders:**
Notices:
Notice of May 13, 2015 .....27851

**14 CFR**
Ch. I .....27853

**15 CFR**
30 .....27853

**21 CFR**
1308 .....27854

**22 CFR**
51 .....27856

**29 CFR**
4022 .....27857

**33 CFR**
100 .....27858

**34 CFR**
**Proposed Rules:**
Ch. III (2 documents) .....27868, 27874

**38 CFR**
**Proposed Rules:**
17 .....27878

**40 CFR**
300 .....27579
**Proposed Rules:**
300 .....27883

**42 CFR**
37 .....27862

**47 CFR**
74 .....27862

**50 CFR**
635 .....27863

Federal Register
Vol. 80, No. 94
Friday, May 15, 2015

# Presidential Documents

**Title 3—**

## The President

**Notice of May 13, 2015**

## Continuation of the National Emergency With Respect to Yemen

On May 16, 2012, by Executive Order 13611, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of certain members of the Government of Yemen and others that threatened Yemen's peace, security, and stability, including by obstructing the implementation of the agreement of November 23, 2011, between the Government of Yemen and those in opposition to it, which provided for a peaceful transition of power that meets the legitimate demands and aspirations of the Yemeni people for change, and by obstructing the political process in Yemen.

The actions and policies of certain members of the Government of Yemen and others in threatening Yemen's peace, security, and stability continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on May 16, 2012, to deal with that threat must continue in effect beyond May 16, 2015. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13611.

This notice shall be published in the **Federal Register** and transmitted to the Congress.

THE WHITE HOUSE,
*May 13, 2015.*

[FR Doc. 2015–11987
Filed 5–14–15; 8:45 am]
Billing code 3295–F5

# Rules and Regulations

Federal Register

Vol. 80, No. 94

Friday, May 15, 2015

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.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Chapter I

### Noise, Fuel Burn, and Emissions Modeling Using the Aviation Environmental Design Tool Version 2b

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Policy statement.

**SUMMARY:** This document provides a statement of FAA policy concerning the required use of the Aviation Environmental Design Tool version 2b (AEDT 2b) to analyze noise, fuel burn, and emissions for FAA actions. The policy statement is intended to ensure consistency and quality of analysis performed to assess noise, fuel burn, and emissions impacts of such actions under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*

**DATES:** Effective May 29, 2015.

**FOR FURTHER INFORMATION CONTACT:** Fabio Grandi, Office of Environment and Energy (AEE), Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591; Telephone: (202) 267–9099.

**SUPPLEMENTARY INFORMATION:**

#### Background

FAA Order 1050.1, Environmental Impacts: Policies and Procedures, describes FAA policies and procedures for compliance with the National Environmental Policy Act (NEPA).

Aircraft noise, air pollutant emissions, and fuel burn are interdependent and occur simultaneously throughout all phases of flight. AEDT 2b is a comprehensive software tool that provides information to FAA stakeholders on each of these specific environmental impacts. AEDT 2b facilitates environmental review activities required under NEPA by consolidating the modeling of these environmental impacts in a single tool. For air traffic airspace and procedure actions, AEDT 2b replaces AEDT 2a, which was released by the FAA in March 2012. For other FAA actions, AEDT 2b replaces the Integrated Noise Model (INM) for analyzing aircraft noise and the Emissions and Dispersion Modeling System (EDMS) for developing emissions inventories and modeling emissions dispersion. AEDT 2b applies to analyses initiated after May 29, 2015.

#### Policy Statement

Effective May 29, 2015, AEDT 2b replaces AEDT 2a, INM, and EDMS as the required tool for noise, fuel burn, and emissions modeling of FAA actions. Consistent with current FAA policy and practice, the use of AEDT 2b is not required for projects whose analysis began before the effective date of this policy. In the event AEDT 2b is updated after the environmental analysis process is underway, the updated version may, but need not, be used to provide additional disclosure concerning noise, fuel burn, and emissions.

This policy statement is issued to ensure consistency and quality of analysis performed to comply with requirements under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*

Issued in Washington, DC, on May 11, 2015.

**Curtis Holsclaw,**

*Deputy Director, Office of Environment and Energy.*

[FR Doc. 2015–11803 Filed 5–14–15; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF COMMERCE

### Bureau of the Census

### 15 CFR Part 30

**[Docket Number: 140821699–5179–02]**

**RIN 0607–AA53**

### Foreign Trade Regulations (FTR): Reinstatement of Exemptions Related to Temporary Exports, Carnets, and Shipments Under a Temporary Import Bond

**AGENCY:** Bureau of the Census, Commerce Department.

**ACTION:** Final rule.

**SUMMARY:** The Bureau of the Census (Census Bureau) issued a final rule amending the Foreign Trade Regulations (FTR) to eliminate the reporting requirement for temporary exports, which includes Carnets, and goods previously imported on a Temporary Import Bond (TIB). This final rule is being implemented to ensure consistency with the Customs Convention on the ATA Carnet for the Temporary Admission of Goods (ATA Convention) and reduce filing burden on the trade community. On September 12, 2014, the Census Bureau published this rule on an interim final basis. The Census Bureau is finalizing this rule without change.

**DATES:** *Effective Date:* This rule is effective May 15, 2015. The interim rule published on September 12, 2014 (79 FR 54588), became effective September 12, 2014.

**FOR FURTHER INFORMATION CONTACT:** Dale C. Kelly, Chief, International Trade Management Division, U.S. Census Bureau, 4600 Silver Hill Road, Room 6K032, Washington, DC 20233–6700, by phone (301) 763–6937, by fax (301) 763–8835, or by email <*dale.c.kelly@census.gov*>.

**SUPPLEMENTARY INFORMATION:**

#### Background

The Census Bureau is responsible for collecting, compiling, and publishing export trade statistics for the United States under the provisions of Title 13, United States Code (U.S.C.), Chapter 9, Section 301(a). The Automated Export System (AES) is the primary instrument used for collecting export trade data, which are used by the Census Bureau

for statistical purposes. Through the AES, the Census Bureau collects Electronic Export Information (EEI), the electronic equivalent of the export data formerly collected on the Shipper's Export Declaration, pursuant to the Foreign Trade Regulations (FTR), Title 15, Code of Federal Regulations (CFR), part 30. Filing in the AES is not required for shipments excluded in Section 30.2(d) and shipments exempted in Subpart D that are not subject to Section 30.2(a)(1)(iv).

The Census Bureau published a Final Rule in the **Federal Register** on March 14, 2013 (78 FR 16366), that removed the exemptions for Carnets and other temporary exports and goods previously imported under a Temporary Import Bond (TIB) exported in the same condition. The Department of the Treasury and members of the trade community raised concerns about the new AES filing requirement for Carnets, which is an international customs and temporary export-import document that is used to clear customs without paying duties and import taxes on merchandise that will be reexported within 12 months. The concerns centered on whether mandatory AES filing for Carnets may be contrary to the ATA Convention, to which the U.S. is a contracting party. In addition, there was concern that unless the exemptions were reinstated, it would be extremely difficult to comply with the FTR, particularly for goods moving on a foreign Carnet. To address these concerns, the Census Bureau and U.S. Customs and Border Protection (CBP) determined it was necessary to reinstate the exemptions from filing for temporary exports, including Carnets, and goods that were previously imported under a TIB for return in the same condition as when exported.

In accordance with the Interim Final Rule published on September 12, 2014, this rule clarifies that the reporting requirement for temporary exports, which includes Carnets, and goods previously imported on a TIB is eliminated. This revision reinstates exemptions for temporary exports/Carnets and for goods that were imported under a TIB for return in the same condition as when imported. The U.S. Department of State and the U.S. Department of Homeland Security concur with the provision contained in this rule.

**Summary of Comments and Responses**

The Census Bureau received one comment on the Interim Final Rule published in the **Federal Register** on September 12, 2014 (79 FR 54588). A summary of the comment and the Census Bureau's response is provided below.

*Comment: Clarify if exporters are required to file Electronic Export Information (EEI) if items are shipped into the U.S. under a foreign obtained ATA Carnet, and then re-exported, never returning to the U.S. Additionally, clarify if exporters are required to file EEI if items are exported under a U.S. obtained ATA Carnet and will be returned within 12 months under the same Carnet.*

*Response:* The Census Bureau clarifies here that reporting of EEI is not required for exports moving under either a U.S. or foreign issued Carnets. All Carnet shipments are exempt from EEI filing under Foreign Trade Regulations, Section 30.37(q) or (r).

**Rulemaking Requirements**

*Administrative Procedure Act*

The Census Bureau finds good cause pursuant to Title 5, U.S.C., 553(b)(3)(B) to waive prior notice and opportunity for public comment, as contrary to the public interest. The Census Bureau is undertaking this amendment in order to reduce filing burden on the trade community and to ensure consistency with the ATA Carnets for the Temporary Admission of Goods (ATA Convention). In particular, this rule reinstates the previous filing exemptions in § 30.37(q) and (r) of the FTR for temporary exports, including Carnets, and goods that were imported under a TIB for return in the same condition as when imported, which will ensure consistency with the ATA Convention, reduce filing requirements, avoid confusion, and ease compliance with the FTR. Additionally, and for similar reasons, the Census Bureau finds good cause pursuant to 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness for this rule. This rule allows for an exemption to the AES filing requirements and imposes no additional requirements or obligations on any member of the public; therefore, delaying its effectiveness is unnecessary.

*Regulatory Flexibility Act*

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this rule will not have a significant impact on a substantial number of small entities.

The purpose and goal of this rule are explained in the preamble, and are not repeated here. This rule does not mandate any new filing requirements and does not directly impact any small or large entities. We received no comments on the certification in the proposed rule; accordingly, no Regulatory Flexibility analysis is required and none has been prepared.

*Executive Orders*

This rule has been determined to be not significant for purposes of Executive Orders 12866 and 13563, and has been drafted according to the requirements of those Executive Orders. It has also been determined that this rule does not contain policies with federalism implications as that term is defined under Executive Order 13132.

*Paperwork Reduction Act*

This rule does not contain any information collection subject to the Paperwork Reduction Act (PRA). However, notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a current and valid Office of Management and Budget (OMB) control number.

**List of Subjects in 15 CFR Part 30**

Economic statistics, Exports, Foreign trade, Reporting and recordkeeping requirements.

## PART 30—FOREIGN TRADE REGULATIONS

■ Accordingly, as discussed above, the Interim Final Rule amending 15 CFR part 30, which was published at 79 FR 54588 on September 12, 2014, is adopted as a final rule without change.

Dated: May 7, 2015.

**John H. Thompson,**

*Director, Bureau of the Census.*

[FR Doc. 2015–11809 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–07–P

---

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1308

**[Docket No. DEA–414]**

## Schedules of Controlled Substances: Extension of Temporary Placement of UR–144, XLR11, and AKB48 in Schedule I of the Controlled Substances Act

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final order.

**SUMMARY:** The Administrator of the Drug Enforcement Administration (DEA) is

issuing this final order to extend the temporary placement of (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR–144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. The current final order temporarily placing UR–144, XLR11, and AKB48 in schedule I is due to expire on May 15, 2015. This final order will extend the temporary scheduling of UR–144, XLR11, and AKB48 to May 15, 2016, or until the permanent scheduling action for these three substances is completed, whichever occurs first.

**DATES:** This final order is effective May 15, 2015.

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:** On May 16, 2013, the Deputy Administrator of the Drug Enforcement Administration published a Final Order in the **Federal Register** (78 FR 28735) amending 21 CFR 1308.11(h) to temporarily place three synthetic cannabinoids, namely (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR–144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48), in schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). That final order, which became effective on the date of publication, was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these three synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expires at the end of two years from the date of issuance of the order scheduling the substance, except that the Attorney General may, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, extend the temporary scheduling of that substance for up to one year. Proceedings for the permanent scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his or her own motion, at the request of the Secretary of Health and Human Services,[1] or on the petition of any interested party.

In this case, the DEA initiated permanent scheduling proceedings on its own motion pursuant to 21 U.S.C. 811(a). The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these three synthetic cannabinoids. On August 31, 2013, the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for UR–144, XLR11, and AKB48, pursuant to 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, the HHS on May 12, 2015, submitted to the Administrator of the DEA its three scientific and medical evaluations entitled, ''Basis For the Recommendation to Place 1-pentyl-1*H*-indol-3-yl 2,2,3,3-tetramethylcyclopropyl methanone (UR–144) and its Salts in schedule I of the Controlled Substances Act (CSA),'' ''Basis For the Recommendation to Place 1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl methanone (XLR11) and its Salts in schedule I of the Controlled Substances Act (CSA),'' and ''Basis For the Recommendation to Place *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48) and its Salts in schedule I of the Controlled Substances Act (CSA).'' Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of UR–144, XLR11, and AKB48 pursuant to 21 U.S.C. 811(c). The DEA is publishing a Notice of Proposed Rulemaking for the Placement of UR–144, XLR11, and AKB48 into schedule I. The Administrator thereby has initiated proceedings regarding UR–144, XLR11, and AKB48 in accordance with 21 U.S.C. 811(a)(1). Therefore, pursuant to 21 U.S.C. 811(h)(2), the Administrator of the DEA hereby orders that the temporary scheduling of UR–144, XLR11, and AKB48, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, be extended to May 15, 2016, or until the proceedings to permanently schedule these three substances is completed, whichever occurs first.

In accordance with this final order, the schedule I requirements for handling UR–144, XLR11, and AKB48, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, will remain in effect until May 15, 2016, or until the permanent scheduling proceeding is completed, whichever occurs first.

## Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Section 201(h) of the CSA, 21 U.S.C. 811(h) also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for up to one year.

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety. Further, the DEA believes that this final order extending the temporary

[1] Because the Secretary of the Department of Health and Human Services has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

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

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to section 808(2) of the Congressional Review Act (CRA), ''any rule for which an agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to maintain the temporary placement of UR–144, XLR11, and AKB48 in schedule I because they pose a public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempted the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moved swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to place these substances in schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this final order extending the temporary scheduling order shall take effect immediately upon its publication. Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801–808), the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

Dated: May 12, 2015.

**Michele M. Leonhart,**

*Administrator.*

[FR Doc. 2015–11765 Filed 5–14–15; 8:45 am]

**BILLING CODE 4410–09–P**

---

## DEPARTMENT OF STATE

## 22 CFR Part 51

**[Public Notice: 9133]**

**RIN 1400–AD83**

## Passports: Official Passports for Officials or Employees of State, Local, Tribal or Territorial Governments Traveling Abroad and Carrying Out Official Duties in Support of the U.S. Government

**AGENCY:** Department of State.

**ACTION:** Interim final rule.

**SUMMARY:** This rule amends the passport rules for the Department of State to authorize issuing an official passport to an official or employee of a state, local, tribal, or territorial government traveling abroad to carry out official duties in support of the U.S. government.

**DATES:** This rule is effective May 15, 2015.

The Department of State will accept comments until July 14, 2015.

**ADDRESSES:** You may make comments by any of the following methods, and you must include the RIN in the subject line of your message.

- *Mail (paper, disk, or CD–ROM submissions):* ATTN: RIN 1400–AD83, Alice Kottmyer, Attorney-Adviser, Office of the Legal Adviser (L/M), U.S. Department of State, Room 4325, 2201 C Street NW., Washington, DC 20520.
- *Email: kottmyeram@state.gov.*
- Persons with access to the Internet may view this rule and submit comments by going to *www.regulations.gov,* and searching for the rule by its RIN, 1400–AD83.

**FOR FURTHER INFORMATION CONTACT:** Alice Kottmyer, Attorney-Adviser, *kottmyeram@state.gov,* 202–647–2318.

**SUPPLEMENTARY INFORMATION:** 22 CFR 51.3(b) provides that an ''official passport'' may be issued to: An official or employee of the U.S. government traveling abroad to carry out official duties; spouses and family members of such persons; and, when authorized by the Department of State, U.S. government contractors traveling abroad to carry out official duties on behalf of the U.S. government.

Increasingly, the federal government utilizes officials or employees of state, local, tribal, and territorial governments in support of federal activities, both domestically and overseas, such as the Federal Bureau of Investigation's Joint Terrorism Task Force. When required to travel internationally in support of such federal activities, these individuals are not currently eligible for official passports. Issuance of an official passport to such individuals signifies to foreign governments that they are carrying out official duties in support of the U.S. government. The activities undertaken by these officials are often of pressing national security, law enforcement, or humanitarian importance and occur with little advance notice. It is in the U.S. government's interest to provide these individuals the travel documents necessary to allow them to travel in a timely manner.

Under 22 U.S.C. 211a *et seq.,* the Secretary of State has the authority to make rules for the granting and issuance of passports. The Department is amending section 51.3(b) of 22 CFR to authorize issuing official passports to an official or employee of a state, local, tribal, or territorial government traveling abroad to carry out official duties in support of the U.S. government.

### Regulatory Findings

*Administrative Procedure Act*

The Department is publishing this rule as an interim final rule, effective on the date of publication, pursuant to the ''good cause'' exemption of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B). The Department finds that delaying the effect of this rule until after notice and comment would be impractical, unnecessary, and contrary to public interest. The Department finds that providing the necessary travel documents to these individuals to allow them to travel in support of U.S. government interests provides a compelling justification for immediate approval of this rule. Therefore, this rule is effective on the date of publication. *See* 5 U.S.C. 553(d). However, the Department solicits—and welcomes—comments on this rulemaking, and will address relevant comments in a final rule.

*Regulatory Flexibility Act*

The Department, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this rule and, by

approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities as defined in 5 U.S.C. 601(6).

*Unfunded Mandates Act of 1995*

This rule will not result in the expenditure by state, local, tribal, or territorial governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

*Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996, since it will not result in an annual effect on the economy of $100 million or more. *See* 5 U.S.C. 804(2).

*Executive Orders 12866 and 13563*

This rule is not economically significant under Executive Order 12866, section 3(f)(1), because it will not have an annual effect on the economy of $100 million or more. The Department expects the rule's impact on the public to be minimal. The Department has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in the Executive Orders.

*Executive Order 13132*

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

*Executive Order 13175—Effect on Tribes*

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

*Paperwork Reduction Act*

This rule does not impose or alter any reporting or record-keeping requirements under the Paperwork Reduction Act.

**List of Subjects in 22 CFR Part 51**

Passports.

Accordingly, for the reasons stated in the preamble, 22 CFR part 51 is amended as follows:

## PART 51—PASSPORTS

■ 1. The authority citation for part 51 continues to read as follows:

**Authority:** 8 U.S.C. 1504; 18 U.S.C. 1621; 22 U.S.C. 211a, 212, 213, 213n (Pub. L. 106–113 Div. B, Sec. 1000(a)(7) [Div. A, Title II, Sec. 236], 113 Stat. 1536, 1501A–430); 214, 214a, 217a, 218, 2651a, 2671(d)(3), 2705, 2714, 2721, & 3926; 26 U.S.C. 6039E; 31 U.S.C. 9701; 42 U.S.C. 652(k) [Div. B, Title V of Pub. L. 103–317, 108 Stat. 1760]; E.O. 11295, Aug. 6, 1966, FR 10603, 3 CFR, 1966–1970 Comp., p. 570; Sec. 1 of Pub. L. 109–210, 120 Stat. 319; Sec. 2 of Pub. L. 109–167, 119 Stat. 3578; Sec. 5 of Pub. L. 109–472, 120 Stat. 3554; Pub. L. 108–447, Div. B, Title IV, Dec. 8, 2004, 118 Stat. 2809; Pub. L. 108–458, 118 Stat. 3638, 3823 (Dec. 17, 2004).

■ 2. Revise paragraph (b) of § 51.3 to read as follows:

**§ 51.3 Types of passports.**

* * * * *

(b) *Official passport.* When authorized by the Department, an official passport may be issued to:

(1) An official or employee of the U.S. government traveling abroad to carry out official duties, and family members of such persons;

(2) A U.S. government contractor traveling abroad to carry out official duties on behalf of the U.S. government; or

(3) An official or employee of a state, local, tribal, or territorial government traveling abroad to carry out official duties in support of the U.S. government.

* * * * *

**Patrick F. Kennedy,**

*Undersecretary For Management.*

[FR Doc. 2015–11687 Filed 5–14–15; 8:45 am]

BILLING CODE 4710–24–P

## PENSION BENEFIT GUARANTY CORPORATION

## 29 CFR Part 4022

## Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in June 2015. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

**DATES:** Effective June 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

**SUPPLEMENTARY INFORMATION:** PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for June 2015.[1]

The June 2015 interest assumptions under the benefit payments regulation will be 0.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

assumptions in effect for May 2015, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during June 2015, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

**List of Subjects in 29 CFR Part 4022**

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

## PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 260, as set forth below, is added to the table.

**Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments**

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | |
|---|---|---|---|---|---|---|---|---|
| | On or after | Before | | $i_1$ | $i_2$ | $i_3$ | $n_1$ | $n_2$ |
| * | * | | * | * | * | * | | * |
| 260 | 6–1–15 | 7–1–15 | 0.75 | 4.00 | 4.00 | 4.00 | 7 | 8 |

■ 3. In appendix C to part 4022, Rate Set 260, as set forth below, is added to the table.

**Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments**

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | |
|---|---|---|---|---|---|---|---|---|
| | On or after | Before | | $i_1$ | $i_2$ | $i_3$ | $n_1$ | $n_2$ |
| * | * | | * | * | * | * | | * |
| 260 | 6–1–15 | 7–1–15 | 0.75 | 4.00 | 4.00 | 4.00 | 7 | 8 |

Issued in Washington, DC, on this 6th day of May 2015.

**Judith Starr,**

*General Counsel, Pension Benefit Guaranty Corporation.*

[FR Doc. 2015–11858 Filed 5–14–15; 8:45 am]

**BILLING CODE 7709–01–P**

## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 100

**[Docket No. USCG–2015–0252]**

## Special Local Regulation; Annual Marine Events on the Colorado River, Between Davis Dam (Bullhead City, Arizona) and Headgate Dam (Parker, Arizona) Within the San Diego Captain of the Port Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Great Western Parker Tube Float marine event and associated waterway special local regulations from 7 a.m. through 4 p.m. on June 6, 2015. This annual marine event occurs in the navigable waters of the Colorado River in Parker, Arizona, covering eight miles of the waterway from the La Paz County Park to the Headgate Dam. This action is necessary to provide for the safety of the participants, crew, spectators, safety vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

**DATES:** The regulations in 33 CFR 100.1102, Table 1, item 9 will be enforced from 7 a.m. through 4 p.m. on June 6, 2015.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this document, call or email Petty Officer Nick Bateman, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, *D11-PF-MarineEventsSanDiego@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulations for the annual Great Western Parker Tube Float in 33 CFR 100.1102, Table 1, Item 9 from 7 a.m. to 4 p.m. on June 6, 2015.

Under the provisions of 33 CFR 100.1102, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area of the Colorado River unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law

enforcement agencies in enforcing this regulation.

This document is issued under authority of 33 CFR 100.1102 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: May 4, 2015.

**J.S. Spaner,**

*Captain, U.S. Coast Guard, Captain of the Port San Diego.*

[FR Doc. 2015–11808 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[EPA–HQ–SFUND–1986–0005; FRL–9927–72–Region 5]**

## National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List: Deletion of the Burrows Sanitation Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the Burrows Sanitation Superfund Site (Site), located in Hartford Township, Van Buren County, Michigan from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Michigan, through the Michigan Department of Environmental Quality (MDEQ), because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** This direct final deletion is effective July 14, 2015 unless EPA receives adverse comments by June 15, 2015. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1986–0005, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments.
- *Email:* Jeffrey Gore, Remedial Project Manager, at *gore.jeffrey@epa.gov* or Cheryl Allen, Community Involvement Coordinator, at *allen.cherly@epa.gov.*
- *Fax:* Gladys Beard, NPL Deletion Process Manager at (312) 697–2077.
- *Mail:* Jeffrey Gore, Remedial Project Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6552, or Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–6196 or (800) 621–8431.
- *Hand delivery:* Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding federal holidays.

*Instructions:* Direct your comments to Docket ID no. EPA–HQ–SFUND–1986–0005. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be 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 the hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at:

- U.S. Environmental Protection Agency—Region 5, 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 353–1063, Hours: Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding federal holidays.
- Hartford Public Library, 15 Franklin Street, Hartford, MI 49057, Phone: (269) 621–3408, Hours: Monday through Wednesday, 10:00 a.m. to 7:00 p.m., Thursday and Friday 10:00 a.m. to 5:00 p.m., Saturday 10:00 a.m. to 5:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Gore, Remedial Project Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6552, or *gore.jeffrey@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Site Deletion
V. Deletion Action

### I. Introduction

EPA Region 5 is publishing this direct final Notice of Deletion of the Burrows Sanitation Superfund Site (Site) from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental

Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This deletion of the Burrows Sanitation Site is issued in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Deletion of Site Listed on the National Priorities List, (49 FR 37070) on September 21, 1989. As described in 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Because EPA considers this action to be noncontroversial and routine, this action will be effective July 14, 2015 unless EPA receives adverse comments by June 15, 2015. Along with this direct final Notice of Deletion, EPA is co-publishing a Notice of Intent to Delete in the *''Proposed Rules''* section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received. There will be no additional opportunity to comment.

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

## II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

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

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

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

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews at these sites even if the site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

## III. Deletion Procedures

The following procedures apply to deletion of the Burrows Sanitation Site:

(1) EPA consulted with the State of Michigan prior to developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published today in the *''Proposed Rules''* section of the **Federal Register**.

(2) EPA has provided the State thirty (30) working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the State, through the MDEQ, has concurred on the deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, the ''Tri-City Record Newspaper''. The newspaper notice announces the 30-day public comment period concerning the Notice of Intent to Delete the Site from the NPL.

(4) EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

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

## IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Burrows Sanitation Superfund Site from the NPL.

### *Site Background and History*

The Burrows Sanitation Site (CERCLIS ID: MID98410617) is approximately 10 acres. The Site is located on 54th Avenue in Hartford Township, Van Buren County, Michigan. The property is located in a rural part of Hartford on a portion of property owned by a resident of Hartford Township. Much of the Site is covered with trees, and there are intermittent open areas to the east and northwest of the Site. The property owner lives west of the Site and another homeowner lives south of the Site across 54th Avenue. There are approximately 150 people living in residences further west along 54th Avenue in a trailer park and a small number of other homes. The residences have historically obtained water from private wells that vary in depth up to 100 feet.

The Site property became contaminated when it was owned by Duane and Evelyn Funk, who agreed to allow Burrows Sanitation, a small septic hauler, to dispose of waste on a remote portion of their property. Burrows Sanitation disposed of wastes on the Site which it had collected from Du-Wel Products Inc., Auto Specialties Manufacturing Company (AUSCO), and Whirlpool Corporation. The wastes were primarily by-products of metal finishing and plating operations, which consisted of hydroxide sludges containing chromium, other metals, as well as some cyanide. The metal hydroxide wastes were deposited in unlined pits when the disposal was taking place between 1970 and 1977.

### *Remedial Investigation and Feasibility Study*

In 1976, the Michigan Department of Natural Resources (MDNR) took samples

from the Site and found elevated levels of copper, chromium and cyanide. In 1984, MDNR conducted further investigations which led it to conclude that the Site posed a human health threat. In July 1984, the Funks, Du-Wel, AUSCO and Whirlpool signed an Administrative Order of Consent (AOC). Pursuant to the AOC, this group of potentially responsible parties (PRPs) proceeded to excavate and remove sludges and contaminated soil from previously identified areas of the Site for off-site disposal.

EPA began remedial planning as the Burrows Sanitation Site was proposed for the NPL on September 8, 1983, (48 FR 40674). The Site was listed on the NPL on September 21, 1989, (49 FR 37070).

*Record of Decision Findings*

The objectives of the 1986 Record of Decision (ROD) for the Site included the following:

The remedial action objectives for the selected remedy at the Burrows Sanitation Site are to protect human health by preventing dermal exposure and ingestion of contaminated sludge and soil from the site, prevent ingestion of contaminated groundwater exceeding drinking water criteria, and prevent exposure of aquatic life from contaminated surface waters. The remedy will achieve Safe Drinking Water Act Primary and Secondary Maximum Contaminant Levels (MCLs) by groundwater treatment and by surface and subsurface soil excavation and off-site disposal.

The components of the 1986 ROD for the Site included the following:

- Purge and treat the contaminated groundwater for approximately 3 years;
- Drain the artificial Northwest Wetland; and
- Remove and treat approximately 250 cubic yards of metal hydroxide sludge from the Spill Area No. 2 and the Northwest Wetland. Dispose of the treated waste at an off-site RCRA facility which is in compliance with EPA policy.

The 1991 Explanation of Significant Differences (ESD) for the Site included the following differences to the 1986 ROD:

- A scaled down groundwater extraction system based on additional groundwater monitoring since the 1986 ROD.
- Off-site treatment of contaminated groundwater instead of on-site treatment.

The 1991 ESD also documented that the soil removal and off-site disposal actions outlined in the 1986 ROD had been completed.

The 1994 ESD for the Site documented the change in the EPA MCL for chromium which was raised from 50 ppb to 100 ppb (effective July 30, 1992).

*Response Actions*

The first phase of the Remedial Action (RA) was completed in May, 1989. During this first phase of the RA, 320 cubic yards of contaminated surface soils and sediments from the spill area identified in the RI/FS were excavated and transported off-site to a RCRA facility. The soil removal was based on soil sampling investigation results completed and reported in 1986, which outlined the area of contaminated soil and how deeper soils for the location at the water table produced chemical concentrations comparable to background. The blockage in the artificial Northwest Wetland was removed and re-channeled. As a result, only the groundwater remained to be treated.

The additional groundwater investigations undertaken in 1989 involved the installation of five new PVC monitoring well nests on the Site. Three rounds of additional groundwater sampling were completed at the Burrows Site in 1990, one each in March, June, and September of that year. Groundwater samples were analyzed for the chemicals of concern, which included dissolved zinc, dissolved chromium, dissolved copper, dissolved lead, and dissolved nickel. Analytical results for the three rounds of groundwater sampling determined that all chemicals of concern were below the groundwater cleanup standards except for an exceedance of dissolved chromium.

The groundwater extraction system including an extraction well, storage tank, and associated equipment for extracting groundwater and removing it for off-site treatment was constructed at the Site between July and September 1991. Groundwater extraction began at the Burrows Site in August of 1992 and continued until December 1993. During that period a total of 2,600,000 gallons of groundwater were extracted and taken for off-site treatment and disposal to the Kalamazoo, Michigan Water Reclamation Plant.

Remedial Action construction activities officially concluded in April of 1993 with the completion and signing of the Preliminary Close-Out Report for the Burrows Site.

*Institutional Controls*

Institutional Controls (''ICs'') are non-engineered instruments, such as administrative and legal controls, that help to minimize the potential for exposure to contamination and that protect the integrity of the remedy. ICs are required to assure the long-term protectiveness for any areas which do not allow for unlimited use and unrestricted exposure (UU/UE). As explained further, none of EPA's decision documents (ROD, ESD, CD or Amended CD) for this Site required ICs in order to assure Site protectiveness since UU/UE would be allowed for all Site areas. The remedy is considered by EPA to be protective of human health and the environment without the need for ICs.

EPA sent out a letter in October 1999 notifying the Burrows Settling Defendants of Completion of Remedial Action under the requirements of the 1992 Amended CD. Site access and use of the land by property owners is now unrestricted, based on completion of the remedial action requirements under the 1992 Amended CD. Both the 1990 CD and the 1992 Amended CD provided that after EPA certification of completion of the remedial action, additional response actions could be required if conditions previously unknown to the United States are discovered or information is received which indicate that the remedial action is not protective of human health and the environment. EPA believes the remedial action completed at this Site is protective of human health and the environment, and it does not plan to require additional remedial action.

*Cleanup Goals*

The post-ROD groundwater monitoring conducted to date by EPA shows that the groundwater has met the drinking water standards outlined in the decision documents and the Amended CD. Therefore, the remedial action conducted at the Site has achieved UU/UE for all site areas. Since the Site remedy has achieved UU/UE, no ICs are required at the Site to assure long-term protectiveness.

MDEQ has conducted independent residential well sampling in the area surrounding the Burrows Site through various County Health Departments from 2002 to 2014. EPA concurred with the MDEQ residential well sampling program. MDEQ contacted the Van Buren-Cass County District Health Department to arrange for sampling of local residential wells beginning in 2002. Van Buren-Cass County District Health Department implemented an annual sampling program for volatile organic compounds (VOCs) at local residential wells. The 2007 sampling results at the five locations were consistent with previous results, which demonstrated that the presence of

volatile organic compounds was not detected at the residential wells sampled. MDEQ stated they planned to include metals in the residential well sampling program beginning in 2008.

Since the 2008 five year review, MDEQ coordinated with Berrien County to collect samples at local residential wells. The 2012 and 2013 results continued to show no detections of volatile organic compounds. Some of the locations were also sampled for metals analysis. None of the metals were detected at concentrations above MCLs although residences exceeded the aesthetic drinking water value of 0.3 mg/l for iron in a range of 0.72–1.42 mg/l. Since no site-related impacts have been seen in the area residential well monitoring conducted over the last several years, MDEQ now believes that it is appropriate to delete the site from the NPL.

While MDEQ had historical concerns regarding the adequacy of groundwater plume characterization, MDEQ now agrees that the implemented remedial actions have been sufficient to address the known risks at the Site.

EPA has determined that the Site is subject to zoning by the local government and the Site is currently zoned for agricultural use. However, limiting the Site to agricultural land use is not a condition of the Superfund remedy.

*Operation and Maintenance*

The implemented remedial actions have been sufficient to address the known risks at the Site. In addition, no-site related impacts have been seen in the residential wells that have been monitored by the MDEQ over the past several years. Effective immediately, the MDEQ will terminate monitoring of the residential wells in the vicinity of the Burrows Sanitation Superfund Site.

*Five-Year Review*

A Five Year Review Report for the Site was completed in February 2013. In the report, EPA viewed the Burrows Sanitation Site as eligible for deletion from the NPL. There were no recommendations and follow-up actions noted in the 2013 Five Year Review Report. Since all clean up goals have been achieved and the site is now unlimited use/unrestricted exposure no additional Five Year Reviews are necessary.

*Community Involvement*

Public participation activities have been satisfied as required in CERCLA Section 113(k), 42 U.S.C. 9613(k), and CERCLA section 117, 42 U.S.C. 9617. Documents in the deletion docket which EPA relied on for recommendation of the deletion of this site from the NPL are available to the public in the information repositories and at *http://www.regulations.gov.*

*Determination That the Site Meets the Criteria for Deletion in the NCP*

The implemented remedy achieves the degree of cleanup specified in the ROD for all pathways of exposure. All selected remedial action objectives and clean-up goals are consistent with agency policy and guidance. No further Superfund response is needed to protect human health and the environment at the Site.

The NCP (40 CFR 300.425(e)) states that a site may be deleted from the NPL when no further response action is appropriate. EPA, in consultation with the State of Michigan, has determined that all required response actions have been implemented and no further response action by the responsible parties is appropriate.

**V. Deletion Action**

EPA, with concurrence from the State of Michigan through the Michigan Department of Environmental Quality, has determined that all appropriate response actions under CERCLA have been completed. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective July 14, 2015 unless EPA receives adverse comments by June 15, 2015. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received. There will be no additional opportunity to comment.

**List of Subjects in 40 CFR Part 300**

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

Dated: April 30, 2015.

**Susan Hedman,**

*Regional Administrator, Region 5.*

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

## PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

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

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

**Appendix B to Part 300—[Amended]**

■ 2. Table 1 of appendix B to part 300 is amended by removing the entry ''MI Burrows Sanitation, Hartford.''

[FR Doc. 2015–11801 Filed 5–14–15; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 37

### Specifications for Medical Examinations of Coal Miners

*CFR Correction*

In Title 42 of the Code of Federal Regulations, Parts 1 to 399, revised as of October 1, 2014, on page 195, in § 37.204, remove the second introductory paragraph.

[FR Doc. 2015–11722 Filed 5–14–15; 8:45 am]

BILLING CODE 1505–01–D

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 74

**[DA 15–486]**

### Suspension of September 1, 2015 Digital Transition Date for Low Power Television and TV Translator Stations

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; suspension of regulations.

**SUMMARY:** In this document, the Media Bureau of the Federal Communications Commission (Commission) announced that, effective May 15, 2015, the September 1, 2015 digital transition date for low power television (LPTV) and TV translator stations is hereby suspended. The Commission will decide on a new transition date in the rulemaking proceeding in MB Docket No. 03–185. Until a decision is reached in the rulemaking and the Commission can determine the effect of the future incentive auction and repacking, LPTV and TV translator stations may delay

completing construction of their digital facilities.

**DATES:** Effective May 15, 2015.

**FOR FURTHER INFORMATION CONTACT:** Shaun Maher, Video Division, Media Bureau, Federal Communications Commission, *Shaun.Maher@fcc.gov,* (202) 418–2324.

**SUPPLEMENTARY INFORMATION:** Effective May 15, 2015, the September 1, 2015 digital transition date for LPTV and TV translator stations is suspended pending final action in the rulemaking proceeding in MB Docket No. 03–185 (79 FR 70824 (Nov. 28, 2014)). The Commission will decide on a new transition date in the rulemaking proceeding in MB Docket No. 03–185. Until a decision is reached in the rulemaking and the Commission can determine the effect of the future incentive auction and repacking, LPTV and TV translator stations may delay completing construction of their digital facilities. Class A television stations are still subject to the September 1, 2015 transition date and analog Class A stations may no longer operate in analog mode after 11:59 p.m., local time, on September 1, 2015. Class A television stations that have not completed constructing their digital facilities by the transition date must go silent while they complete construction.

Class A television stations are also reminded that the Commission has designated May 29, 2015, as the Pre-Auction Licensing Deadline by which Class A television stations' digital facilities must be licensed in order to be eligible for protection in the repacking process that will be part of the incentive auction. In order for a Class A television station's digital facility to be afforded protection in the repacking process, it must be licensed or have an application for a license to cover on file by the Pre-Auction Licensing Deadline. Although Class A television stations may wait until the September 1, 2015, digital transition deadline to complete construction and license their digital facilities, those that do not have their digital facilities licensed by May 29, 2015, will be afforded protection based only on the coverage area and population served by their analog facilities.

### List of Subjects in 47 CFR Part 74

Television.

Federal Communications Commission.

**Barbara Kreisman,**

*Chief, Video Division, Media Bureau.*

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 74 as follows:

## PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

■ 1. The authority citation for part 74 continues to read as follows:

**Authority:** 47 U.S.C. 154, 302a, 303, 307, 309, 336 and 554.

■ 2. In § 74.731, revise paragraph (l) to read as follows:

**§ 74.731 Purpose and permissible service.**

* * * * *

(l) After 11:59 p.m. local time on September 1, 2015, Class A television stations may no longer operate any facility in analog (NTSC) mode.

[FR Doc. 2015–10226 Filed 5–14–15; 8:45 am]

BILLING CODE 6712–01–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 635

**[Docket No. 120328229–4949–02]**

**RIN 0648–XD902**

## Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

**ACTION:** Temporary rule; General and Angling category retention limit adjustments for Atlantic bluefin tuna (BFT); Purse Seine category BFT fishery start date.

**SUMMARY:** NMFS is adjusting the General category BFT daily retention limit for June 1 through August 31, 2015, and the Angling category BFT daily retention limit for the remainder of 2015. In addition, NMFS is announcing July 6, 2015, as the start date for this year's Purse Seine category fishery. The General category daily retention limit is adjusted to four large medium or giant BFT. This adjustment applies to Atlantic tunas General category (commercial) permitted vessels and HMS Charter/Headboat category permitted vessels when fishing commercially for BFT. The Angling category daily retention limit is adjusted to: Two school BFT and one large school/small medium BFT per vessel per day/trip for charter vessels (*i.e.,* those with HMS Charter/Headboat permits when fishing recreationally); and one school BFT and one large school/small medium BFT per vessel per day/trip for private vessels (*i.e.,* those with HMS Angling category permits). These retention limits are effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeted fishing for BFT. These actions are based on consideration of the applicable regulatory determination criteria.

**DATES:** The Angling category retention limit is effective May 15, 2015 through December 31, 2015. The General category retention limit is effective June 1, 2015, through August 31, 2015. The Purse Seine category fishery will start July 6, 2015, and continue through December 31, 2015.

**FOR FURTHER INFORMATION CONTACT:** Sarah McLaughlin or Brad McHale, 978–281–9260.

**SUPPLEMENTARY INFORMATION:** Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014), and in accordance with implementing regulations. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The currently codified baseline U.S. quota is 923.7 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). Among other things, Amendment 7 revised the allocations to all quota categories, effective January 1, 2015. See § 635.27(a).

The 2015 BFT fishing year, which is managed on a calendar-year basis and subject to an annual quota, began January 1, 2015. The Angling category

season opened January 1, 2015, and continues through December 31, 2015. The size classes of BFT are summarized in Table 1. Please note that large school and small medium BFT traditionally have been managed as one size class, as described below, *i.e.,* a limit of one large school/small medium BFT (measuring 47 to less than 73 inches).

TABLE 1—BFT SIZE CLASSES

| Size class | Curved fork length |
|---|---|
| School | 27 to less than 47 inches (68.5 to less than 119 cm). |
| Large school | 47 to less than 59 inches (119 to less than 150 cm). |
| Small medium | 59 to less than 73 inches (150 to less than 185 cm). |
| Large medium | 73 to less than 81 inches (185 to less than 206 cm). |
| Giant | 81 inches or greater (206 cm or greater). |

Currently, the default Angling category daily retention limit of one school, large school, or small medium BFT applies (§ 635.23(b)(2)). This retention limit applies to HMS Angling and to HMS Charter/Headboat category permitted vessels (when fishing recreationally for BFT). In 2014, NMFS adjusted the daily retention limit from the default level to one school BFT and one large school/small medium BFT for private vessels (*i.e.,* those with HMS Angling category permits); and two school BFT and one large school/small medium BFT for charter vessels (*i.e.,* those with HMS Charter/Headboat permits when fishing recreationally), effective May 8 through December 31 (79 FR 25707, May 6, 2014).

The General category season was open January 1 through March 31, 2015 (the ''January'' category time period), resumes on June 1, 2015, and continues through December 31, 2015. Unless changed, the General category daily retention limit would be the default retention limit of one large medium or giant BFT per vessel per day/trip (§ 635.23(a)(2)). The General category default retention limit applies to General category permitted vessels and to HMS Charter/Headboat category permitted vessels when fishing commercially for BFT.

For the 2014 fishing year, NMFS adjusted the General category limit from the default level of one large medium or giant BFT as follows: Two large medium or giant BFT for January (78 FR 77362, December 23, 2013), four large medium or giant BFT for June through August (79 FR 30745, May 29, 2014), and four large medium or giant BFT for September through December (79 FR 50854, August 26, 2014). NMFS adjusted the daily retention limit for the 2015 January subquota period from the default level of one large medium or giant BFT to three large medium or giant BFT (79 FR 77943, December 29, 2014). In that action, NMFS also transferred 21 mt of BFT quota from the December 2015 subquota to the January 2015 subquota period.

**Adjustment of Daily Retention Limits**

In adjusting the daily retention limits in this action, NMFS considered the factors required by regulatory criteria, as discussed in more detail, below.

Under § 635.23(a)(4), NMFS may increase or decrease the General category daily retention limit of large medium and giant BFT over a range of zero to a maximum of five per vessel. Under § 635.23(b)(3), NMFS may increase or decrease the Angling category retention limit for any size class of BFT. Any adjustments to retention limits must be based on consideration of the relevant criteria provided under § 635.27(a)(8), which include: The usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock; the catches of the particular category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made; the projected ability of the vessels fishing under the particular category quota to harvest the additional amount of BFT before the end of the fishing year; the estimated amounts by which quotas for other gear categories of the fishery might be exceeded; effects of the adjustment on BFT rebuilding and overfishing; effects of the adjustment on accomplishing the objectives of the fishery management plan; variations in seasonal distribution, abundance, or migration patterns of BFT; effects of catch rates in one area precluding vessels in another area from having a reasonable opportunity to harvest a portion of the category's quota; review of dealer reports, daily landing trends, and the availability of the BFT on the fishing grounds; optimizing fishing opportunity; accounting for dead discards, facilitating quota monitoring, supporting other fishing monitoring programs through quota allocations and/or generation of revenue; and support of research through quota allocations and/or generation of revenue. Recreational retention limits may be adjusted separately for specific vessel type, such as private vessels, headboats, or charter vessels.

NMFS has considered these criteria and their applicability to the General category BFT retention limit for June–August 2015 and to the Angling category BFT retention limit for the remainder of 2015. These considerations include, but are not limited to, the following. Biological samples collected from BFT landed by recreational and commercial fishermen and provided by BFT dealers continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. A principal consideration is the objective of providing opportunities to harvest the full Angling category quota and the June—August General category subquota without exceeding them based upon the 2006 Consolidated HMS FMP goal: ''Consistent with other objectives of this FMP, to manage Atlantic HMS fisheries for continuing optimum yield so as to provide the greatest overall benefit to the Nation, particularly with respect to food production, providing recreational opportunities, preserving traditional fisheries, and taking into account the protection of marine ecosystems.'' It is also important that NMFS constrain landings to BFT subquotas both to adhere to the FMP quota allocations and to ensure that landings are as consistent as possible with the pattern of fishing mortality (*e.g.,* fish caught at each age) that was assumed in the projections of stock rebuilding.

NMFS also considered the fact that it is in the process of proposing a rule that would implement and give domestic effect to the 2014 ICCAT recommendation on western Atlantic BFT management, which increased the U.S. BFT quota for 2015 and 2016 by 14 percent from the 2014 level. The domestic subquotas to be proposed in that action would result from application of the allocation process established in Amendment 7 to the increased U.S. quota. As explained below, however, the retention limits being set in this action are not dependent on those quota increases.

The currently codified Angling category quota is 168.6 mt (94.9 mt for school BFT, 69.8 mt for large school/small medium BFT, and 3.9 mt for large medium/giant BFT). If the proposed quota rule (discussed above) is finalized as proposed, the Angling category quota could be expected to increase to 195.2 mt (108.4 mt for school BFT, 82.3 mt for large school/small medium BFT, and 4.5 mt for large medium/giant BFT). The currently codified General category quota is 403 mt. Each of the General category time periods (''January,'' June through August, September, October

through November, and December) is allocated a portion of the annual General category quota. The codified June through August subquota is 201.5 mt. Under the proposed quota rule NMFS is preparing, the General category quota would increase to 466.7 mt and the June through August General category subquota would increase to 233.3 mt.

*Angling Category Daily Retention Limit Adjustment*

In addition to the considerations that apply to both the General and Angling category retention limit adjustments, described above, NMFS has considered the regulatory determination criteria and their applicability to the Angling category BFT retention limit. These considerations include, but are not limited to, the following. Under the Angling category limits in effect for 2014 (described above), Angling category landings were approximately 112 mt (62 percent of the 182-mt subquota), with 24.7 mt of school BFT landed (26 percent of the 94.9-mt school BFT subquota). Given that the landings fell short of the available quota, that additional quota is anticipated to be available this year as a result of the 2014 ICCAT recommendation, and considering the regulatory criteria above, NMFS has determined that the Angling category retention limit applicable to participants on HMS Angling and HMS Charter/Headboat category permitted vessels should be adjusted upwards from the default level. NMFS has also concluded that implementation of separate limits for private and charter/headboat vessels remains appropriate, recognizing the different nature, socio-economic needs, and recent landings results of the two components of the recreational BFT fishery. For example, charter operators historically have indicated that a multi-fish retention limit is vital to their ability to attract customers. In addition, Large Pelagics Survey estimates indicate that charter/headboat BFT landings averaged approximately 30 percent of recent recreational landings for 2013 through 2014, with the remaining 70 percent landed by private vessels.

Therefore, for private vessels (*i.e.,* those with HMS Angling category permits), the limit is one school BFT and one large school/small medium BFT per vessel per day/trip (*i.e.,* one BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches). For charter vessels (*i.e.,* those with HMS Charter/Headboat permits), the limit is two school BFT and one large school/small medium BFT per vessel per day/trip when fishing recreationally for BFT (*i.e.,* two BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches). These retention limits are effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeted fishing for BFT. Regardless of the duration of a fishing trip, the daily retention limit applies upon landing.

NMFS anticipates that the BFT daily retention limits in this action will result in landings during 2015 that would not exceed the available subquotas (both those codified and as expected to be proposed). Lower retention limits could result in substantial underharvest of the codified Angling category subquota, and increasing the daily limits further may risk exceeding the available quota, contrary to the objectives of the 2006 Consolidated HMS FMP, as amended. Further increasing the school BFT retention limit for private and charter vessels could be possible without exceeding the annual school BFT subquota (both the amount currently codified and the amount that NMFS anticipates proposing in the quota rule shortly), given that the 2014 Angling category landings represented 66 percent of the currently-codified Angling category quota and 57 percent of the soon-to-be-proposed Angling category quota. Nevertheless, NMFS has concluded that retention limits consistent with last year's remain appropriate given the need to not exceed the ICCAT tolerance limit on school BFT and other considerations, such as potential effort shifts to BFT fishing as a result of current, reduced recreational retention limits for New England groundfish and striped bass. NMFS will monitor 2015 landings closely and will make further adjustments, including closure if necessary, with an inseason action if warranted.

*General Category Daily Retention Limit Adjustment*

In addition to the considerations that apply to both the General and Angling category retention limit adjustments, described above, NMFS has considered the regulatory determination criteria and their applicability to the General category BFT retention limit for the June—August 2015 General category fishery. These considerations include, but are not limited to, the following. Commercial-size BFT are anticipated to migrate to the fishing grounds off the northeast U.S. coast by early June. Based on General category landings rates during the June through August time period over the last several years, it is highly unlikely that the June through August subquota (both the currently codified amount and the amount that will be proposed) will be filled with the default daily retention limit of one BFT per vessel, and it may not be filled at a three-BFT limit if recent patterns of BFT availability and landings rates continue. During the June—August 2013 period, under a three-fish limit, BFT landings were approximately 108 mt (50 percent of the available subquota for that period). In the June—August 2014 period, under a four-fish limit, BFT landings were approximately 107 mt (49 percent of the subquota). For the entire 2014 fishing year, 94.6 percent of the General category quota was filled.

A limit lower than four fish could result in unused quota being added to the later portion of the General category season (*i.e.,* rolling forward to the subsequent subquota time period). Increasing the daily retention limit from the default may mitigate rolling an excessive amount of unused quota from one time-period subquota to the next. However, increasing the daily limit to five fish may risk exceeding the available June—August subquota. NMFS has also received comment over recent years from General category fishery participants and BFT dealers that a five-fish limit at this time of year may negatively affect market prices as the fish quality tends to be lower earlier in the year. Increasing the daily retention limit to four fish will increase the likelihood that the General category BFT landings will approach, but not exceed, the annual quota, as well as increase the opportunity for catching BFT harvest during the June through August subquota period. Increasing (and sometimes maximizing) opportunity within each subquota period is also important because of the migratory nature and seasonal distribution of BFT. In a particular geographic region, or waters accessible from a particular port, the amount of fishing opportunity for BFT may be constrained by the short amount of time the BFT are present.

Based on these considerations, NMFS has determined that a four-fish General category retention limit is warranted. It would provide a reasonable opportunity to harvest the U.S. quota of BFT, without exceeding it, while maintaining an equitable distribution of fishing opportunities; help achieve optimum yield in the General category BFT fishery; allow the collection of a broad range of data for stock monitoring purposes; and be consistent with the objectives of the 2006 Consolidated HMS FMP, as amended. Therefore, NMFS increases the General category retention limit from the default limit to four large medium or giant BFT per

vessel per day/trip, effective June 1, 2015, through August 31, 2015.

Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example, during the June through August period, whether a vessel fishing under the General category limit takes a two-day trip or makes two trips in one day, the day/trip limit of four fish applies and may not be exceeded upon landing. This General category retention limit is effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeting fishing for BFT, and applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels fishing commercially for BFT.

These retention limit adjustments are intended to provide a reasonable opportunity to harvest the U.S. quota of BFT without exceeding it, while maintaining an equitable distribution of fishing opportunities; and to be consistent with the objectives of the 2006 Consolidated HMS FMP, as amended. The adjustments are consistent with the quotas previously implemented and analyzed in the 2011 BFT quota final rule, as adjusted by the final rule to implement Amendment 7, and consistent with the objectives of the 2006 Consolidated HMS FMP and amendments, and are not expected to negatively impact stock health. The adjustments also are supported by the Supplemental Environmental Assessment prepared for the 2013 quota specifications and the Final Environmental Impact Statement/Regulatory Impact Review/Final Regulatory Flexibility Analysis prepared for Amendment 7.

*Monitoring and Reporting*

NMFS will continue to monitor the BFT fisheries closely through the mandatory landings and catch reports. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. General, HMS Charter/Headboat, Harpoon, and Angling category vessel owners are required to report the catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov.*

HMS Angling and HMS Charter/Headboat category permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. Anglers are also reminded that all BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *www.nmfs.noaa.gov/sfa/hms/.*

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional retention limit adjustments or closures are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. Subsequent actions, if any, will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (888) 872–8862 or (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

**Purse Seine Category BFT Fishery Start Date**

Amendment 7 revised the fishery start date to be set annually by NMFS between June 1 and August 15. The start date was made more flexible to optimize fishing opportunity for Purse Seine category vessels and to minimize potential gear conflicts or the impacts of oversupply on the market.

Under § 635.27(a)(4), NMFS may start the Purse Seine category BFT fishery between June 1 and August 15. Annually, NMFS will make a determination when the Purse Seine category fishery will start, based on variations in seasonal distribution, abundance or migration patterns of BFT, cumulative and projected landings in other commercial fishing categories, the potential for gear conflicts on the fishing grounds, or market impacts due to oversupply. In the past, NMFS has received comments from fishermen that use commercial handgear expressing concern that purse seining activity may disrupt their ability to capture BFT at the surface (*i.e.,* harpoon gear) if purse seining occurs early in the season (*i.e.,* in the month of June) and for rod and reel fishing if the activities are concentrated later in the season (*i.e.,* mid-July through the fall). NMFS has also received comments expressing concern about potential oversupply of the market by purse seine vessel(s) offloading a large amount of fish at once, and, as a result, lower ex-vessel prices, particularly early in the season (*i.e.,* the month of June) when fish quality and prices tend to be lower.

In 2004 through 2014, the Purse Seine category BFT fishery started on July 15 of each year (68 FR 74504, December 24, 2003). Since 2006, Purse Seine category landings have been low relative to available quota for the category, with no BFT harvested in 2008, 2010, and 2011.

Based on these considerations, NMFS has determined that a 2015 Purse Seine category BFT fishery start date of July 6 is warranted. The July 6 start date would alleviate issues with potential gear conflicts in June and early July (including over the July 4 holiday weekend) and concerns about market impacts caused by potential oversupply, thus balancing the needs of the Harpoon, General, and Purse Seine category fisheries. It would provide a reasonable opportunity to harvest the U.S. BFT quota, without exceeding it, while maintaining an equitable distribution of fishing opportunities; help achieve optimum yield in the Purse Seine category BFT fishery; and be consistent with the objectives of the 2006 Consolidated HMS FMP, as amended. Therefore, NMFS sets the purse seine fishery start date for July 6, 2015, through December 31, 2015.

*Monitoring and Reporting*

NMFS will continue to monitor the Purse Seine category BFT fishery closely through the mandatory landings and catch reports. Consistent with the regulations implementing Amendment 7, purse seine vessel operators are required to use their vessel monitoring system (VMS) to report to NMFS as follows: For each purse seine set, as instructed by NMFS, the date and area of the set, and the length of all BFT retained (actual), and the length of all BFT discarded dead or alive (approximate), must be reported within 12 hours of the completion of the retrieval of each set.

**Classification**

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP, as amended, provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Based on available BFT quotas, fishery performance in recent years, the availability of BFT on the fishing grounds, among other considerations, adjustment to the General and Angling category BFT daily retention limits from the default levels is warranted. Analysis of available data shows that adjustment to the BFT daily retention limit from the default level would result in minimal

risks of exceeding the ICCAT-allocated quota. The regulations implementing the 2006 Consolidated HMS FMP, as amended, also provide the flexibility to set the Purse Seine category BFT fishery start date between June 1 and August 15 based on variations in seasonal distribution, abundance or migration patterns of BFT, cumulative and projected landings in other commercial fishing categories, the potential for gear conflicts on the fishing grounds, or market impacts due to oversupply. NMFS provides notification of retention limit adjustments and the purse seine fishery start date by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on *hmspermits.noaa.gov.*

Delays in increasing these retention limits would adversely affect those HMS General, Angling, and Charter/Headboat category vessels that would otherwise have an opportunity to harvest more than the default retention limit of one school, large school, or small medium BFT per day/trip for the Angling category, or one BFT per day/trip for the General category, and may exacerbate the problem of low catch rates and quota rollovers. In addition, delays in starting the Purse Seine category BFT fishery would adversely affect those purse seine vessels that would otherwise harvest BFT during that time. Limited opportunities to harvest the respective quotas may have negative social and economic impacts for U.S. fishermen that depend upon catching the available quota within the time periods designated in the 2006 Consolidated HMS FMP, as amended. Purse Seine category fishermen need sufficient advance notice of the specific start date of the fishery in order to plan fishing trips, including meeting VMS requirements and arranging for observer coverage. Adjustment of the General category retention limit needs to be effective June 1, 2015, or as soon as possible thereafter, to minimize any unnecessary disruption in fishing patterns, to allow the impacted sectors to benefit from the adjustment, and to not preclude fishing opportunities for fishermen who have access to the fishery only during this time period. In addition, fisheries under the Angling category daily retention limit are currently underway and delaying this action would be contrary to the public interest. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under §§ 635.23(a)(4), 635.23(b)(3), and 635.27(a)(4) and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: May 12, 2015.

**Emily H. Menashes,**

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

[FR Doc. 2015–11791 Filed 5–12–15; 4:15 pm]

BILLING CODE 3510–22–P

# Proposed Rules

Federal Register
Vol. 80, No. 94
Friday, May 15, 2015

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

## DEPARTMENT OF EDUCATION

### 34 CFR Chapter III

**[Docket ID ED–2015–OSERS–0034]**

### Proposed Priority—Rehabilitation Training: Vocational Rehabilitation Technical Assistance Center—Youth With Disabilities

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Proposed priority.

[CFDA Number: 84.264H.]

**SUMMARY:** The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Rehabilitation Training program. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2015 and later years. This priority is designed to ensure that professionals working in State vocational rehabilitation (VR) agencies receive the technical assistance they need to provide youth with disabilities with services and supports that lead to postsecondary education and competitive integrated employment.

**DATES:** We must receive your comments on or before June 15, 2015.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Are you new to the site?''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Tara Jordan, U.S. Department of Education, 400 Maryland Avenue SW., Room 5040, Potomac Center Plaza (PCP), Washington, DC 20202–2800.

**Privacy Note:** The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:** Tara Jordan. Telephone: (202) 245–7341 or by email: *tara.jordan@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:**

*Invitation to Comment:* We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific section of the proposed priority that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about these proposed regulations by accessing Regulations.gov. You may also inspect the comments in person in room 5040, 550 12th Street SW., PCP, Washington, DC, 20202–2800, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

*Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record:* On request we will provide an appropriate accommodation or auxiliary aid 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 accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

*Purpose of Program:* Under the Rehabilitation Act of 1973 (Rehabilitation Act), as amended by the Workforce Innovation and Opportunity Act (WIOA), the Rehabilitation Services Administration makes grants to States and public or nonprofit agencies and organizations (including institutions of higher education) to support projects that provide training, traineeships, and technical assistance designed to increase the numbers of, and improve the skills of, qualified personnel (especially rehabilitation counselors) who are trained to: provide vocational, medical, social, and psychological rehabilitation services to individuals with disabilities; assist individuals with communication and related disorders; and provide other services authorized under the Rehabilitation Act.

**Program Authority:** 29 U.S.C. 772(a)(1).

*Applicable Program Regulations:* 34 CFR part 385.

*Proposed Priority:*

This notice contains one proposed priority.

*Vocational Rehabilitation Technical Assistance Center—Youth with Disabilities (VRTAC–Y).*

*Background:*

State vocational rehabilitation (VR) agencies provide employment-related services to students and youth with disabilities in order to facilitate a smooth transition from school to post-school activities and to assist them in obtaining the training and skills they need to achieve competitive integrated employment. The Workforce Innovation and Opportunity Act (WIOA) amended the Rehabilitation Act by expanding the kinds of services that State VR agencies may provide to students and youth with disabilities and adding definitions of the terms ''student with a disability'' and ''youth with a disability''.

The new definition for ''student with a disability'' at section 7(37)(A) of the Rehabilitation Act, as amended by WIOA, renumbered here for ease of reading, is an individual with a disability who—

(a)(1)(i) is not younger than the earliest age for the provision of transition services under section

614(d)(1)(A)(i)(VIII) of the Individuals with Disabilities Education Act (20 U.S.C. 1414(d)(1)(A)(i)(VIII); or

(ii) if the State involved elects to use a lower minimum age for receipt of pre-employment transition services under this Act, is not younger than that minimum age; and

(2)(i) is not older than 21 years of age; or

(ii) if the State law for the State provides for a higher maximum age for receipt of services under the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*), is not older than that maximum age; and

(b)(1) is eligible for, and receiving, special education or related services under Part B of the Individuals with Disabilities Education Act (20 U.S.C. 1411 *et seq.*); or

(2) is an individual with a disability, for purposes of section 504.

The new definition for ''youth with a disability'' at section 7(42)(A) of the Rehabilitation Act, as amended by WIOA, also renumbered here for ease of reading, is an individual with a disability who (a) is not younger than 14 years of age; (b) is not older than 24 years of age.

Historically, State VR agencies have had difficulty in locating and serving students with disabilities who are not served under the IDEA and youth with disabilities who are no longer in school. Therefore, the proposed Vocational Rehabilitation Technical Assistance Center for Youth with Disabilities (VRTAC–Y) would focus on providing technical assistance to State VR agencies on locating and serving students with disabilities not served under the IDEA and youth with disabilities who are not enrolled in school and who are not employed. Additionally, the National Technical Assistance Center on Transition, jointly funded by the Office of Special Education Programs (OSEP) and the Rehabilitation Services Administration (RSA), already provides technical assistance on the provision of transition services to students who are served under the IDEA.

The difficulty in locating and serving students with disabilities who are not served under the IDEA arises because these students usually do not have a lead teacher or advocate in the school system with the responsibility to facilitate the connection of students with disabilities to VR or to other services in the community. Without these connections, students may not obtain the necessary services and supports they need to be successful in education and training programs or competitive integrated employment after exiting high school.

Similarly, youth with disabilities who are not enrolled in school are usually not connected to the local adult service systems and, as a consequence, are not referred to the State VR agency for transition services or to other programs and services they may need. In particular, youth with disabilities who are high school dropouts, exiting the foster care system, or juvenile offenders are at high risk for not transitioning into successful and economically self-sufficient adult lives, and the consequences of this failure are considerable. Students with disabilities, particularly students with emotional or behavioral disabilities and learning disabilities, are at greater risk for dropping out of school (Lehr, et al. 2004). Youth with disabilities who drop out of high school experience substantial economic and social problems, including unemployment, poverty, homelessness, and incarceration. In addition, youth with disabilities who age out of the foster care system or are exiting correctional facilities often have multiple needs and may face additional challenges in connecting to appropriate community services and supports.

There are a number of promising and innovative practices aimed at assisting students and youth with disabilities to succeed in transitioning to adulthood, particularly education and competitive integrated employment, which are useful to State VR agencies. ''Guideposts for Success'' is a comprehensive resource of such practices focusing on the needs of youth with disabilities and vulnerable populations, such as youth in foster care and youth involved or at risk of becoming involved in the juvenile justice system (see *http://www.ncwd-youth.info/topic/guideposts*). Early transition planning, information about career options and exposure to the world of work, including structured internships, the involvement of family members, and/or other caring adults can assist students and youth with disabilities to meet the challenges they face and may lead to better post-school outcomes. Students with disabilities who are engaged in courses that they choose and that they believe will prepare them for life, including career technical and cooperative education classes, are less likely to drop out (Dunn, Chambers and Rabren, 2004).

In addition, collaboration among State educational agencies (SEAs), local educational agencies (LEAs), State VR agencies, and other service providers helps to ensure the delivery of coordinated transition services. (Landmark, et al., 2010; National Council on Disability, 2008). Systems coordination promotes easier access to services for students and youth with disabilities and strengthens results and accountability leading to more positive outcomes (Russ and Fryar 2014).

The proposed VRTAC–Y would provide training and technical assistance to State VR agencies to assist them in identifying and serving students and youth with disabilities; designing and implementing collaborative and integrative approaches to serving students and youth with disabilities; and strengthening and expanding coordination of services to students and youth with disabilities, particularly those not served under the IDEA.

*References:*

Dunn, C., Chambers, D. and Rabren, K. (2004). Variables Affecting Students' Decision to Drop Out of School. Remedial and Special Education, 25, 314.

Landmark, L.J., Ju, S., and Zhang, D. (2010). Substantiated Best Practices in Transition: Fifteen Plus Years Later. Career Development for Exceptional Individuals, 33(3).

Lehr, C.A., Johnson, D.R., Bremer, C.D., Cosio, A., & Thompson, M. (2004). Essential tools: Increasing rates of school completion: Moving from policy and research to practice. Minneapolis, MN: University of Minnesota, Institute on Community Integration, National Center on Secondary Education and Transition.

National Council on Disability (2008). The Rehabilitation Act: Outcomes for Transition-Age Youth. Retrieved from: *http://www.ncd.gov/policy/employment.*

Russ, E. and Fryar, G. (December 2014). Creating Access to Opportunities for Youth in Transition from Foster Care: An AYPF Policy Brief. American Youth Policy Forum.

*Proposed Priority:*

The purpose of this proposed priority is to fund a cooperative agreement to establish a Vocational Rehabilitation Technical Assistance Center—Youth with Disabilities (VRTAC–Y). The focus of this proposed priority is to provide technical assistance (TA) to State vocational rehabilitation (VR) agencies to improve services to and outcomes of: (1) students with disabilities, as defined in section 7(37) of the Rehabilitation Act, who are in school and who are not receiving services under the IDEA; and (2) youth with disabilities, as defined in section 7(42) of the Rehabilitation Act, who are no longer in school and who are not employed. For purposes of this priority, ''Students and youth with disabilities'' refers to these two groups.

The VRTAC–Y is designed to achieve, at a minimum, the following outcomes:

(a) Assist State VR agencies to identify and meet the VR needs of students and youth with disabilities consistent with

section 101(a)(15) of the Rehabilitation Act;

(b) Improve the ability of State VR agencies to develop partnerships with State and local agencies, service providers, or other entities to ensure that students and youth with disabilities are referred for VR services and have access to coordinated supports, services, training, and employment opportunities, including: (1) increasing the number of referrals and applications received by State VR agencies from agencies, service providers and others serving students and youth with disabilities; and (2) increasing the number of students and youth with disabilities receiving VR services;

(c) Improve the ability of VR personnel to develop individualized plans for employment that ensure the successful transition of students and youth with disabilities and the achievement of post-school goals; and

(d) Increase the number of students and youth with disabilities served by VR agencies (particularly dropouts, foster care youth and youth involved in the correctional system) who are engaged in education and training programs leading to the attainment of postsecondary skills and credentials needed for employment in high-demand occupations.

**Topic Areas**

Under this proposed priority, the VRTAC–Y must develop and provide training and TA to State VR agency staff and related rehabilitation professionals and service providers in the following topic areas:

(a) Developing and maintaining formal and informal partnerships and relationships with relevant stakeholders (including, but not limited to, school systems, institutions of higher education (IHEs), State and local service agencies, community rehabilitation programs, correctional facilities and programs, and employers) to increase referral of students and youth with disabilities to the State VR system for the supports and services they need to achieve competitive integrated employment;

(b) Developing and implementing outreach policies and procedures using evidence-based and promising practices that ensure that students and youth with disabilities in the State are located, identified, and evaluated for services; and

(c) Developing and implementing collaborative and coordinated service strategies, such as higher education and training services; and internship, apprenticeship, and other work experience services designed to increase the number of students and youth with disabilities who are served by the State VR agency who obtain competitive integrated employment.

**Project Activities**

Under this proposed priority, the VRTAC–Y must, at a minimum, conduct the following activities:

**Knowledge Development Activities**

(a) In the first year, collect information from the literature and from existing Federal, State, and other programs on evidence-based and promising practices relevant to the work of the VRTAC–Y and make this information publicly available in a searchable, accessible, and useful format. The VRTAC–Y must review, at a minimum:

(1) State VR agency State plan descriptions of outreach plans and procedures, coordination and collaboration with other agencies, and coordination and collaboration with education officials relating to students and youth with disabilities;

(2) State VR agency formal interagency agreements with SEAs for the coordination of transition services, including the provision of pre-employment transition services;

(3) The results of State VR agency monitoring conducted by RSA, when available;

(4) State VR agency program and performance data; and

(5) Information on promising practices and VR needs of students and youth with disabilities from TA centers that serve relevant public and private non-profit agencies, as well as existing RSA and OSEP TA centers and RSA and OSEP Parent Training and Information Centers.

(b) In the first year, conduct a survey of relevant stakeholders and VR service providers to identify TA needs that the VRTAC–Y can meet and develop a process by which TA solutions can be offered to State VR agencies and their partners. The VRTAC–Y must survey, at a minimum:

(1) State VR agency staff;

(2) Relevant RSA staff;

(3) Grantees of the National Institute on Disability, Independent Living, and Rehabilitation Research that are researching topics related to the work of the VRTAC–Y; and

(4) Educators or other professionals conducting research on topics related to the work of the VRTAC–Y.

**Technical Assistance and Dissemination Activities**

(a) Over the five-year grant period, provide intensive TA to a minimum of 10 State VR agencies and their associated rehabilitation professionals and service providers in the topic areas set out in this proposed priority.[1] In each of the second, third, fourth, and fifth years of the project, the VRTAC–Y must provide intensive TA to at least two different State VR agencies. Applicants must clearly describe the application process and selection criteria for the State VR agencies that would receive intensive TA. Such TA must include:

(1) For topic area (a)—

(i) Identification of key stakeholders in the State or region who can improve the State VR agency's ability to perform outreach activities and meet the employment and training needs of students and youth with disabilities;

(ii) Effective marketing and outreach to school and community services personnel, such as how best to present information about VR supports, training, and programming for students and youth with disabilities; and

(iii) How to develop formal and informal service and outreach agreements with relevant stakeholders to meet the employment and training needs of students and youth with disabilities.

(2) For topic area (b)—

(i) How to conduct an analysis and assessment of outreach strategies to determine gaps between service delivery systems, as well as the need for coordinated services and supports across service systems for students and youth with disabilities;

(ii) How to access and leverage partnerships across agencies and service delivery systems to increase the number of students and youth with disabilities provided with relevant and accessible information regarding services available through the State VR agency.

(3) For topic area (c)—

(i) Evidence-based and promising practices in the development and implementation of vocational services to meet the employment and training needs of students and youth with disabilities;

(ii) How to incorporate students and youth with disabilities into training programs in which they have been historically underrepresented; and

(iii) How to assist students and youth with disabilities in accessing customized vocational, occupational, or

[1] For the purposes of this proposed priority, ''intensive TA'' means TA services often provided on-site and requiring a stable, ongoing relationship between the TA Center staff and the TA recipient. ''TA services'' are defined as a negotiated series of activities designed to reach a valued outcome. Intensive TA should result in changes to policy, programs, practices, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

certification training or other career training that is directly responsive to employer needs and hiring requirements, including, but not limited to, training offered by providers under the Carl D. Perkins Career and Technical Education Improvement Act, H–1B Ready to Work Partnership Grants, and Trade Adjustment Assistance Community College and Career Training Grants, including two-year and four-year IHEs.

(b) In the first year, develop and refine a minimum of five curriculum guides for VR staff training in topics related to the work of the VRTAC–Y, which must include:

(1) Partnership development across service delivery systems for purposes of leveraging resources and coordinating supports, services, training, and employment opportunities for students and youth with disabilities;

(2) Development, implementation, and dissemination of effective model outreach strategies, policies, and procedures to improve access for students and youth with disabilities to VR services and supports;

(3) Development of customized training, other career training, and work experience programs for students and youth with disabilities;

(4) Development and delivery of support services to providers of career training programs that facilitate completion of training and result in competitive integrated employment for students and youth with disabilities; and

(5) Delivery of support services to employers who hire students and youth with disabilities from customized or career training programs or who offer internships and work experience opportunities.

(c) Provide a range of targeted and general TA products and services on the topic areas in this proposed priority. Such TA must include, at a minimum, the following activities:

(1) Developing and maintaining a state-of-the-art information technology (IT) platform sufficient to support Webinars, teleconferences, video conferences, and other virtual methods of dissemination of information and TA;

**Note:** All products produced by the VRTAC–Y must meet government and industry-recognized standards for accessibility, including section 508 of the Rehabilitation Act. The VRTAC–Y may either develop a new platform or system, or modify existing platforms or systems, so long as the requirements of the priority are met.

(2) Ensuring that all TA products are sent to the National Center for Rehabilitation Training Materials, including: course curricula; audiovisual materials; Webinars; examples of emerging and best practices related to the topic areas in this proposed priority; and any other TA products; and

(3) Providing a minimum of four Webinars or video conferences on each of the topic areas in this proposed priority to describe and disseminate information about emerging and promising practices in each area.

**Coordination Activities**

(a) Establish a community of practice for all interested State VR agencies that will act as a vehicle for communication, exchange of information among State VR agencies and partners, and a forum for sharing the results of TA projects that are in progress or have been completed. Such community of practice must be focused on partnerships across service systems, outreach and identification strategies for students and youth with disabilities, and the development and provision of vocational services and vocational training to students and youth with disabilities.

(b) Communicate and coordinate, on an ongoing basis, with other Department-funded projects and those supported by the Departments of Labor and Commerce; and

(c) Maintain ongoing communications with the RSA project officer.

**Application Requirements**

To be funded under this proposed priority, applicants must meet the proposed application requirements in this proposed priority. RSA encourages innovative approaches to meet these requirements. The proposed application requirements are:

(a) Demonstrate, in the narrative section of the application, under ''Significance of the Project,'' how the proposed project will—

(1) Address State VR agencies' capacity to meet the employment and training needs of students and youth with disabilities. To meet this requirement, the applicant must:

(i) Demonstrate knowledge of emerging and best practices in conducting outreach and providing VR services to students and youth with disabilities;

(ii) Demonstrate knowledge of current applicable Federal statutes and regulations, current RSA guidance, and State and Federal initiatives designed to improve employment outcomes for students and youth with disabilities; and

(iii) Present information about the difficulties that State VR agencies and service providers have encountered in developing and implementing effective outreach and service delivery plans for students and youth with disabilities; and

(2) Result in increases in both the number of students and youth with disabilities receiving services from State VR agencies and related agencies and the number and quality of employment outcomes in competitive integrated employment for students and youth with disabilities;

(b) Demonstrate, in the narrative section of the application, under ''Quality of Project Services,'' how the proposed project will—

(1) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes;

(ii) A plan for how the proposed project will achieve its intended outcomes; and

(iii) A plan for communicating and coordinating with key staff in State VR agencies, State and local partner programs, advocates for students and youth with disabilities, RSA partners such as the Council of State Administrators of Vocational Rehabilitation (CSAVR), the National Council of State Agencies for the Blind (NCSAB), and other TA Centers and relevant programs within the Departments of Education, Labor, and Commerce;

(2) Use a conceptual framework to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

(3) Be based on current research and make use of evidence-based and promising practices. To meet this requirement, the applicant must describe—

(i) The current research on emerging, promising, and evidence-based practices in the topic areas in this proposed priority;

(ii) How the current research about adult learning principles and implementation science will inform the proposed TA; and

(iii) How the proposed project will incorporate current research and evidence-based practices in the development and delivery of its products and services;

(4) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this

requirement, the applicant must describe—

(i) Its proposed activities to identify or develop the knowledge base on emerging and promising practices in the topic areas in this proposed priority;

(ii) Its proposed approach to universal, general TA; [2]

(iii) Its proposed approach to targeted, specialized TA,[3] which must identify—

(A) The intended recipients of the products and services under this approach; and

(B) Its proposed approach to measure the readiness of State VR agencies to work with the proposed project, assessing, at a minimum, their current infrastructure, available resources, and ability to effectively respond to the TA, as appropriate;

(iv) Its proposed approach to intensive, sustained TA, which must identify—

(A) The intended recipients of the products and services under this approach;

(B) Its proposed approach to measure the readiness of the State VR agencies to work with the proposed project including the State VR agencies' commitment to the TA initiatives, appropriateness of the initiatives, current infrastructure, available resources, and ability to respond effectively to the TA, as applicable;

(C) Its proposed plan for assisting State VR agencies to build training systems that include professional development based on adult learning principles and coaching; and

(D) Its proposed plan for developing intensive TA agreements with State VR agencies to provide intensive, sustained TA. The plan must describe how the intensive TA agreements will outline the purposes of the TA, the intended outcomes of the TA, and the measurable objectives of the TA that will be evaluated;

(5) Develop products and implement services to maximize the project's efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes; and

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration;

(c) Demonstrate, in the narrative section of the application under ''Quality of the Evaluation Plan,'' how the proposed project will—

(1) Measure and track the effectiveness of the TA provided. To meet this requirement, the applicant must describe its proposed approach to—

(i) Collecting data on the effectiveness of each TA activity from State VR agencies, partners, or other sources, as appropriate; and

(ii) Analyzing data and determining the effectiveness of each TA activity, including any proposed standards or targets for determining effectiveness. At a minimum, the VRTAC–Y must analyze data on school and service system referrals to State VR agencies and employment outcomes of students and youth with disabilities, including type of employment, wages, hours worked, weeks of employment, and public benefits received;

(2) Collect and analyze data on specific and measurable goals, objectives, and intended outcomes of the project, including measuring and tracking the effectiveness of the TA provided. To address this requirement, the applicant must describe—

(i) Its proposed evaluation methodologies, including instruments, data collection methods, and analyses;

(ii) Its proposed standards or targets for determining effectiveness;

(iii) How it will use the evaluation results to examine the effectiveness of its implementation and its progress toward achieving the intended outcomes; and

(iv) How the methods of evaluation will produce quantitative and qualitative data that demonstrate whether the project and individual TA activities achieved their intended outcomes;

(d) Demonstrate, in the narrative section of the application under ''Adequacy of Project Resources,'' how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have historically been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to provide TA to State VR agencies and their partners in each of the topic areas in this proposed priority and to achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits;

(e) Demonstrate, in the narrative section of the application under ''Quality of the Management Plan,'' how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors that will be allocated to the project and how these allocations are appropriate and adequate to achieve the project's intended outcomes, including an assurance that such personnel will have adequate availability to ensure timely communications with stakeholders and RSA;

(3) The proposed management plan will ensure that the products and services provided are of high quality; and

(4) The proposed project will benefit from a diversity of perspectives, including those of State and local personnel, TA providers, researchers, and policy makers, among others, in its development and operation.

*Types of Priorities:*

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

*Absolute priority:* Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

*Competitive preference priority:* Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional

[2] For the purposes of this priority, ''universal, general technical assistance'' means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's Web site by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

[3] For the purposes of this priority, ''targeted, specialized technical assistance'' means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

*Invitational priority:* Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

**Note:** This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

## Executive Orders 12866 and 13563

*Regulatory Impact Analysis*

Under Executive Order 12866, the Secretary must determine whether this proposed regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority only on a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Rehabilitation Training program have been well established over the years through the successful completion of similar projects. This proposed priority will better prepare State VR agency personnel to assist the students and youth with disabilities who are the focus of this priority to achieve competitive integrated employment in today's challenging labor market.

*Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

*Accessible Format:* Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

*Electronic Access to This Document:* 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 via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site 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). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 12, 2015.

**Sue Swenson,**

*Acting Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 2015–11826 Filed 5–14–15; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF EDUCATION

### 34 CFR Chapter III

**[Docket ID ED–2015–OSERS–0061]**

### Proposed Priority and Definitions—Demonstration and Training Program: Career Pathways for Individuals With Disabilities

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Proposed priority and definitions.

[CFDA Number: 84.235N.]

**SUMMARY:** The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority and definitions under the Demonstration and Training program. The Assistant Secretary may use this priority and one or more of these definitions for competitions in fiscal year (FY) 2015 and later years. This priority and these definitions are designed to support projects that develop and implement career pathways for individuals with disabilities.

**DATES:** We must receive your comments on or before June 15, 2015.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Are you new to the site?''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to RoseAnn Ashby, U.S. Department of Education, 400 Maryland Avenue SW., Room 5055, Potomac Center Plaza (PCP), Washington, DC 20202–2800.

**Privacy Note:** The U.S. Department of Education's (Department's) policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:** RoseAnn Ashby. Telephone: (202) 245–7258 or by email: *roseann.ashby@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:**

*Invitation to Comment:* We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority and definitions, we urge you to identify clearly the specific section of the proposed priority or definition that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority and these proposed definitions. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice by accessing Regulations.gov. You may also inspect the comments in person in Room 5055, 550 12th Street SW., PCP, Washington, DC 20202–2800, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

*Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record:* On request we will provide an appropriate accommodation or auxiliary aid 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 accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

*Purpose of Program:* The purpose of the Demonstration and Training Program is to provide competitive grants to, or enter into contracts with, eligible entities to expand and improve rehabilitation and other services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act), or to further the purposes and policies in sections 2(b) and 2(c) of the Rehabilitation Act by supporting activities that increase the provision, extent, availability, scope, and quality of rehabilitation services under the Rehabilitation Act.

**Program Authority:** 29 U.S.C. 773(b).

*Applicable Program Regulations:* 34 CFR part 373.

**Proposed Priority**

This notice contains one proposed priority.

*Career Pathways for Individuals With Disabilities*

Background

Despite largely positive trends in U.S. economic indicators, including a declining trend in the overall unemployment rate,[1] employers report difficulty finding workers with the specific skills and knowledge that they need. In the recovering economy, it is critical that employers have access to highly skilled workers to meet the challenges of today's labor market. Individuals with disabilities comprise a large group of potential employees who, with the necessary skills and credentials, could help fill this unmet need and participate fully in the economy and our society.

With nearly one in five people in the United States identified as having a disability, strategies designed to encourage the growth of the recovering economy will need to include initiatives to tap the skills and knowledge of this underutilized human resource. While recent data show that the labor force participation rate for working-age people with disabilities is beginning to increase, it is far below the rate for individuals without disabilities (31.1 percent for individuals with disabilities compared to 75.7 percent for the working-age people without disabilities).[2]

One strategy for assisting individuals to acquire skills relevant in today's economy is to develop and use a career pathway. By preparing workers for high-demand occupations, career pathways offer a promising approach for improving the foundation skills of young adults and low-skilled adults, including individuals with disabilities, and the Nation's overall economic prosperity. A ''career pathway,'' as defined in section 3(7) of the Workforce Innovation and Opportunity Act (WIOA), is a combination of rigorous and high-quality education, training, and other services that is aligned with the skill needs of industries in the State

[1] The Employment Situation, U.S. Department of Labor, Bureau of Labor Statistics, 2015.

[2] nTIDE Jobs Report; Kessler Foundation and University of New Hampshire, 2015.

or regional economy and that enables individuals to attain a recognized postsecondary credential that will help them enter or advance within a specific occupation or occupational cluster. This definition also is included in the Definitions section of this notice.

One of the benefits of a career pathways approach is the integration of educational instruction, workforce development, and human and social services and supports that are linked to labor market trends and employer needs leading to stackable credentials.[3] The career pathways approach has wide support among the Federal Departments of Labor, Education, and Health and Human Services (see *http://www2.ed.gov/about/offices/list/ovae/ten-attachment.pdf*). In addition to issuing joint guidance, these agencies developed technical assistance resources that promote the use of career pathways approaches. For example, under the ''Designing Instruction for Career Pathways'' initiative, the Department's Office of Career, Technical, and Adult Education made available resources to help expand the creation of career pathways systems in States and local areas. The Department of Labor (DOL) developed a comprehensive set of technical assistance tools, including the ''Career Pathways Framework and Toolkit'' and the ''Competency Model Clearinghouse.'' These materials can be found at DOL's Community of Practice Web site, at: *learnwork.workforce3one.org.*

The State Vocational Rehabilitation (VR) Services program is the primary Federal vehicle in the workforce development system for assisting individuals with disabilities, particularly individuals with the most significant disabilities, to prepare for, obtain, retain, or advance in competitive integrated employment. As required partners in the one-stop service delivery system established under WIOA for accessing employment and training services, State VR agencies must coordinate and collaborate with other entities, including employers, educational and non-educational agencies working with youth, and other agencies and programs providing services to individuals with disabilities. However, to increase the employment of individuals with disabilities, State VR agencies need employment approaches that are effective in assisting individuals to attain knowledge and skills that can lead to employment in high-demand occupations.

Through this proposed priority, the Office of Special Education and Rehabilitative Services seeks to support collaborations between State VR agencies, secondary and postsecondary educational institutions, workforce centers and other training providers, human and social service agencies, employers, and other community stakeholders. These collaborations will demonstrate how career pathways can help individuals with disabilities served by State VR agencies to acquire the marketable skills and to attain recognized postsecondary credentials that lead to employment in high-demand occupations.

References

U.S. Census Bureau (2012). Nearly 1 in 5 People Have a Disability in the U.S., Census Bureau Reports. News Release. *https://www.census.gov/newsroom/releases/archives/miscellaneous/cb12-134.html*.

U.S. Department of Labor, Bureau of Labor Statistics (2015). The Employment Situation, Economic News Release (3/6/15). *http://www.bls.gov/news.release/empsit.nr0.htm*.

U.S. Department of Labor Training and Employment Guidance Letter (TEGL) No. 15–10, Increasing Credential, Degree, and Certificate Attainment by Participants of the Public Workforce System.

Kessler Foundation and University of New Hampshire. (2015). nTIDE Jobs Report: Rising Tide Continues to Raise Workers with Disabilities, Monthly Update. (3/6/2015). *http://us2.campaign-archive1.com/?u=767afbe8bd6db50de03889 b40&id=eb4a1ab921&e=e235f2eadb.*

Proposed Priority

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority designed to demonstrate promising practices in the use of career pathways (as defined in this notice) in order to improve employment outcomes for individuals with disabilities (as defined in this notice). Specifically, the purpose of the proposed priority is to establish a model demonstration project designed to promote State vocational rehabilitation (VR) agency partnerships in the development and use of career pathways to help individuals with disabilities eligible for VR services, including youth with disabilities (as defined in this notice), to acquire marketable skills and recognized postsecondary credentials (as defined in this notice).

*Eligible Applicants:* Under this proposed priority, an applicant must be either a State VR agency or a consortium of State VR agencies.

*Project Requirements:* Under this proposed priority, the model demonstration proposed by an applicant must, at a minimum—

(a) Develop and implement a collaborative model project demonstrating promising practices and strategies in the use of career pathways to improve the skills of individuals with disabilities, including youth with disabilities, and help them attain credentials that lead to employment in high-demand occupations. The model must be implemented at multiple sites to ensure its replicability. The career pathways must lead to one or more occupational clusters (as defined in this notice);

(b) Establish partnerships between the VR agencies, employers, agencies, and entities that are critical to the development of career pathways and the alignment of education, training, employment, and human and social services. At a minimum, the partnership should include representatives from the public educational agency or agencies responsible for providing transition services to students with disabilities under the Individuals with Disabilities Education Act and representatives from two-year and four-year institutions of higher education, American Job Centers, workforce training providers (including apprenticeship providers), and employers who will work in collaboration to develop and provide postsecondary education and training for individuals with disabilities served under this project;

(c) Include the following career pathway components:

(1) Alignment of secondary and postsecondary education, training, employment, and human services with the skill needs of targeted industry sectors important to local, regional, or State economies;

(2) Rigorous, sequential, connected, and efficient curricula that connect basic education and skills training courses and that integrate education with training;

(3) Multiple entry and exit points for individuals with disabilities entering and exiting training;

(4) Comprehensive support services that are designed to ensure the individual's success in completing education and training programs:

(i) Financial supports, career counseling, child care, and transportation;

[3] The U.S. Department of Labor defines a ''stackable credential'' as one that is ''part of a sequence of credentials that can be accumulated over time to build up an individual's qualifications and help them to move along a career pathway or up a career ladder to different and potentially higher-paying jobs.'' (U.S. Department of Labor Training and Employment Guidance Letter (TEGL) No. 15–10; *http://wdr.doleta.gov/directives/attach/TEGL15-10.pdf*)

(ii) Educational supports (*e.g.,* tutors, on-campus supports such as writing labs, math labs, and disability services);

(iii) Self-advocacy training (*e.g.,* understanding how to request services and supports needed in the transition from secondary to post-secondary education and employment, and increasing knowledge of rights under disability laws); and

(iv) Appropriate assistive technology services and devices;

(5) Flexible design of education and training programs and services to meet the particular needs of individuals with disabilities, including flexible work schedules, alternative class times and locations, and the innovative use of technology;

(6) Education and training programs that focus on the attainment of secondary education and recognized postsecondary credentials, sector-specific employment, educational advancement over time and employment within a sector, including curriculum and instructional strategies designed to develop the following knowledge and skills:

(i) Career exploration and career readiness skills;

(ii) Basic academic skills needed to demonstrate knowledge competencies in an occupation or occupational cluster, including remedial skills to address gaps in basic reading, writing, and math skills;

(iii) Career and technical skills leading to employment in technical careers, including employment in the skilled trades; and

(iv) Soft skills (*e.g.,* understanding learning styles, identifying strengths and weaknesses);

(d) Collaborate with other federally-funded career pathway initiatives conducting activities relevant to the work of its proposed project; and

(e) Develop and conduct an evaluation of the project's performance in achieving project goals and objectives, including an evaluation of the effectiveness of the practices and strategies implemented by the project.

*Application Requirements:* To be considered for funding under this proposed priority, an applicant must meet the proposed application requirements in this proposed priority. The proposed application requirements are:

(a) A detailed review of the literature that supports the potential effectiveness of the proposed model, its components, and processes to improve outcomes for individuals with disabilities;

(b) A logic model that communicates how the demonstration project will achieve its outcomes and provides a framework for project evaluation. The logic model must depict, at a minimum, the goals, activities, outputs, and outcomes of the proposed model demonstration project;

(c) A description of the applicant's plan for implementing the project, including a description of—

(1) A cohesive, articulated model of partnership and coordination among the participating agencies and organizations;

(2) The coordinated set of promising practices and strategies in the use and development of career pathways that are aligned with employment, training, and education programs and reflect the needs of employers and individuals with disabilities; and

(3) How the proposed project will—

(i) Identify local workforce needs, aligned with the skill needs of targeted industry sectors important to local, regional, or State economies;

(ii) Involve employers in the project design and in partnering with project staff to develop integrated community settings for assessments, job shadowing, internships, apprenticeships, and other paid and unpaid work experiences that are designed to lead to competitive integrated employment for individuals with disabilities, including youth with disabilities;

(iii) Conduct outreach activities to identify individuals with disabilities for whom the career pathways approach would enable them to achieve competitive integrated employment in career clusters identified in their application; and

(iv) Develop strategies for involving families that will increase the likelihood for successful educational and employment outcomes for individuals with disabilities.

(d) The methods and criteria that will be used to select the sites at which the project activities will be implemented;

(e) Evidence (*e.g.,* letter of support or draft agreement) that the State VR agency has specific agreements with its partners in the development and implementation of the project;

(f) A plan for evaluating the project's performance, including an evaluation of the effectiveness of the practices and strategies implemented by the project, in achieving project goals and objectives. Specifically, the evaluation plan must include a description of:

(1) Project goals, measurable objectives, and operational definitions;

(2) the data to be collected;

(3) how the data will be analyzed; and

(4) the outcomes for individuals with disabilities served by the project compared with the outcomes of individuals with disabilities not receiving project services.

(g) At a minimum, the data collected must include:

(1) the relevant RSA–911 Case Service Report data for each project participant;

(2) the number of participants who enter a career pathway;

(3) the number of participants who complete training in a career pathway; and

(4) the number of participants who attain a recognized postsecondary credential and the type of credentials attained.

(h) A plan for systematic dissemination of project findings and knowledge gained that will assist State and local agencies in adapting or replicating the model career pathways developed and implemented by the project, which could include elements such as development of a Web site, community of practice, and participation in national and State conferences;

(i) An assurance that the employment goal for all individuals served under this priority will be competitive integrated employment, including customized or supported employment; and

(j) An assurance that the project will collaborate with other federally-funded career pathway initiatives conducting activities relevant to its work.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

*Absolute priority:* Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

*Competitive preference priority:* Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

*Invitational priority:* Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

**Proposed Definitions**

*Background*

The following definitions are proposed to ensure that applicants have a clear understanding of how we are using these terms in the priority. These definitions are based on defined statutory terms in WIOA, the Rehabilitation Act and definitions that the Department uses or relies on in other contexts. Although we cannot make changes to the text of statutory definitions, we announce them along with our other proposed definitions below to provide notice of our intent to use them in the context of this program.

*Proposed Definitions*

The Assistant Secretary proposes the following definitions for this program. We may apply one or more of these definitions in any year in which this program is in effect.

*Career Pathway* means a combination of rigorous and high-quality education, training, and other services that—

(a) Aligns with the skill needs of industries in the economy of the State or regional economy involved;

(b) Prepares an individual to be successful in any of a full range of secondary or postsecondary education options, including apprenticeships registered under the Act of August 16, 1937 (commonly known as the ''National Apprenticeship Act''; 50 Stat. 664, chapter 663; 29 U.S.C. 50 *et seq.*);

(c) Includes counseling to support an individual in achieving the individual's education and career goals;

(d) Includes, as appropriate, education offered concurrently with and in the same context as workforce preparation activities and training for a specific occupation or occupational cluster;

(e) Organizes education, training, and other services to meet the particular needs of an individual in a manner that accelerates the educational and career advancement of the individual to the extent practicable;

(f) Enables an individual to attain a secondary school diploma or its recognized equivalent, and at least one recognized postsecondary credential; and

(g) Helps an individual enter or advance within a specific occupation or occupational cluster. Source: Section 3(7) of WIOA.

*Competitive integrated employment* means work that is performed on a full-time or part-time basis (including self-employment)—

(a) For which an individual—

(1) Is compensated at a rate that—

(i)(A) Shall be not less than the higher of the rate specified in section 6(a)(1) of the Fair Labor Standards Act of 1938 (29 U.S.C. 206(a)(1)) or the rate specified in the applicable State or local minimum wage law; and

(B) Is not less than the customary rate paid by the employer for the same or similar work performed by other employees who are not individuals with disabilities, and who are similarly situated in similar occupations by the same employer and who have similar training, experience, and skills; or

(ii) In the case of an individual who is self-employed, yields an income that is comparable to the income received by other individuals who are not individuals with disabilities, and who are self-employed in similar occupations or on similar tasks and who have similar training, experience, and skills; and

(2) Is eligible for the level of benefits provided to other employees;

(b) That is at a location where the employee interacts with other persons who are not individuals with disabilities (not including supervisory personnel or individuals who are providing services to such employee) to the same extent that individuals who are not individuals with disabilities and who are in comparable positions interact with other persons; and

(c) That, as appropriate, presents opportunities for advancement that are similar to those for other employees who are not individuals with disabilities and who have similar positions. Source: Section 7(5) of the Rehabilitation Act.

*Individual with a disability* means any individual who—

(a) Has a physical or mental impairment which for such individual constitutes or results in a substantial impediment to employment; and

(b) Can benefit in terms of an employment outcome from vocational rehabilitation services provided pursuant to Title I, III, or VI of the Rehabilitation Act. Source: Section 7(20) of the Rehabilitation Act.

*Occupational cluster* means a group of occupations and broad industries based on common knowledge and skills, job requirements or worker characteristics. Source: Adopted from Career Pathways Toolkit, DOL.

*Recognized postsecondary credential* means a credential consisting of an industry-recognized certificate or certification, a certificate of completion of an apprenticeship, a license recognized by the State involved or Federal Government, or an associate or baccalaureate degree. Source: Section 3(52) of WIOA.

*Youth with a disability* means an individual with a disability who—

(a) Is not younger than 14 years of age; and

(b) Is not older than 24 years of age.

Source: Section 7(42) of the Rehabilitation Act.

*Final Priority*

We will announce the final priority and definitions in a notice in the **Federal Register**. We will determine the final priority and definitions after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

**Note:** This notice does *not* solicit applications. In any year in which we choose to use one or more of this priority and these proposed definitions, we invite applications through a notice in the **Federal Register**.

**Executive Orders 12866 and 13563**

*Regulatory Impact Analysis*

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive Order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority and these proposed definitions only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Demonstration and Training program have been well established over the years through the successful completion of similar projects. For example, the projects first funded in FY 2007 to demonstrate collaborative practices that lead to postsecondary education and employment of youth with disabilities have served as a rich source of practices for the VR field. This proposed priority and these proposed definitions would promote projects that would serve as models in developing and implementing career pathways for individuals with disabilities that could be replicated by other State VR agencies so that such agencies could improve employment outcomes for individuals with disabilities.

*Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

*Accessible Format:* Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

*Electronic Access to This Document:* 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 via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site 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). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 12, 2015.

**Sue Swenson,**

*Acting Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 2015–11829 Filed 5–14–15; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 17

**RIN 2900–AP09**

## Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans—Covered Birth Defects and Spina Bifida

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations concerning the provisions of health care to birth children of Vietnam veterans and veterans of covered service in Korea diagnosed with spina bifida, except for spina bifida occulta, and certain other birth defects. The proposed changes would more clearly define the types of health care VA provides, including day health care and health-related services, which VA would define as homemaker or home health aide services that provide assistance with Activities of Daily Living or Instrumental Activities of Daily Living that have therapeutic value. We would also make changes to the list of health care services that require preauthorization by VA.

**DATES:** Comments must be received by VA on or before July 14, 2015.

**ADDRESSES:** Written comments may be submitted through *www.regulations.gov;* by mail or hand-delivery to the Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP09—Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans—Covered Birth Defects and Spina Bifida.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket—Management System (FDMS) at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Karyn Barrett, Director, Program Administration Directorate, Chief Business Office Purchased Care (10NB3), Veterans Health Administration, Department of Veterans

Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (303) 331–7500. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Chapter 18 of title 38, United States Code, provides for benefits for certain birth children of Vietnam veterans and veterans of covered service in Korea who have been diagnosed with spina bifida, except spina bifida occulta, and certain other birth defects. These benefits include: (1) Monthly monetary allowances for various disability levels; (2) health care; and (3) vocational training and rehabilitation. VA has published regulations at 38 CFR 17.900 through 17.905 concerning health care for children authorized by 38 U.S.C. 1803 as well as 1813. Section 1803(a) authorizes VA to provide a child of a Vietnam veteran who is suffering from spina bifida, except spina bifida occulta, with health care. Section 1813(a) authorizes VA to provide a child of a woman Vietnam veteran who has been diagnosed with certain other birth defects needed health care for that child's covered birth defects or any disability that is associated with those birth defects. The definitions in section 1803(c) apply to both programs, with two narrow exceptions that are not relevant to this rulemaking.

The term ''health care'' under 38 U.S.C. 1803(c)(1) is defined as home care, hospital care, nursing home care, outpatient care, preventive care, habilitative and rehabilitative care, case management, and respite care. In addition, health care includes the training of appropriate members of a child's family or household in the care of the child; the provision of pharmaceuticals; supplies (including continence-related supplies such as catheters, pads, and diapers); equipment (including durable medical equipment); devices; appliances; assistive technology; and direct transportation costs to and from approved health care providers (including any necessary costs for meals and lodging en route and accompaniment by an attendant or attendants). Certain of these benefits and services require preauthorization by VA under § 17.902.

Health care that is not provided directly by VA must be provided by contract with an approved health care provider or by other arrangement with an approved health care provider. Under current § 17.900, ''approved health care provider'' means a health care provider currently approved by the Center for Medicare and Medicaid Services (CMS), Department of Defense TRICARE Program, Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), Joint Commission on Accreditation of Health Care Organizations (JCAHO), or currently approved for providing health care under a license or certificate issued by a governmental entity with jurisdiction. An entity or individual will be deemed to be an approved health care provider only when acting within the scope of the approval, license, or certificate. We do not propose any substantive changes to the definition of approved health care provider, but the definition is relevant here because we use the term in this rulemaking.

VA has identified a need for certain types of care for these individuals and intends to clarify in regulation which services are authorized by 38 U.S.C. 1803 and 1813 and will be provided under this authority. We propose to amend our regulations to clarify what services constitute health care under § 17.900 and to revise the list of health care services that would require preauthorization by VA under § 17.902. These proposed changes are based on an advisory opinion from VA's Office of the General Counsel (OGC). VAOPGCADV 5–2013 (June 13, 2013). OGC issued this advisory opinion in response to a VA request for clarification as to whether VA is authorized by 38 U.S.C. 1803 to provide various types of health care services.

One of those services is day health care. Day health care services are a non-institutional alternative to nursing home care, and we believe that VA may reimburse these services under its authority in 38 U.S.C. 1803 to provide outpatient care and respite care.

Outpatient care is defined at 38 U.S.C. 1803(c)(6) to mean care and treatment of a disability, and preventive health services, furnished to an individual other than hospital care or nursing home care. The phrase ''care and treatment'' is also found in the definitions of hospital care, nursing home care, and preventive care at 38 U.S.C. 1803(c)(4) through (7). The inclusion of the phrase ''care and treatment'' in the definitions of the categories of authorized health care services indicates legislative intent that a therapeutic component must be part of the service provided. Accordingly, we would define day health care to also include a therapeutic component. So defined, we believe that day health care services constitute care and treatment furnished outside of hospital care or nursing home care, and, therefore, that VA may provide day health care services as part of outpatient care authorized by 38 U.S.C. 1803. We would also amend the definition of outpatient care to include day health care as an authorized health care service.

We would define ''day health care'' to mean a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care services contemplated under this proposal are equivalent to adult day health care provided to disabled veterans under 38 CFR 17.111(c)(1), except that such services would be provided to individuals who are not veterans. The essential features are the therapeutic focus of the day health care services and provision of these services in a congregate setting.

Current § 17.900 defines outpatient care as care and treatment, including preventive health services, furnished to a child other than hospital care or nursing home care. We would amend this definition to include day health care to clarify that day health care is a component of outpatient care.

Day health care services are also a component of respite care. Respite care is currently defined at § 17.900 as care furnished by an approved health care provider on an intermittent basis for a limited period to an individual who resides primarily in a private residence when such care will help the individual continue residing in such private residence. Respite care is a service that pays for a person to come to an individual beneficiary's home or for the beneficiary to go to a program, including a day health care program, so the family caregiver can have a period during which the caregiver is not responsible to provide care to the beneficiary. Respite care allows the family caregiver to run errands without worrying about leaving the beneficiary alone at home. Respite care can help reduce the stress a family caregiver may feel when managing a beneficiary's long-term care needs at home, and therefore can improve the quality of care and assistance provided to the beneficiary. VA currently provides day health care to eligible beneficiaries as an element of respite care, and we would amend the definition of respite care to clarify that it is an included service.

Home care is defined at § 17.900 as medical care, habilitative and rehabilitative care, preventive health services, and health-related services furnished to a child in the child's home or other place of residence. The regulation also defines habilitative and rehabilitative care and preventive health care but does not define ''health-related services.'' We propose to define ''health-

related services'' for purposes of §§ 17.900 through 17.905 as homemaker or home health aide services furnished in the individual's home or other place of residence to the extent that those services involve assistance with Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs) that have therapeutic value. This is consistent with VA's interpretation of the term ''health-related services'' as it is used relative to care provided to veterans.

We would define homemaker services to mean certain activities that help to maintain a safe, healthy environment for an individual in the home or other place of residence. Such services contribute to the prevention, delay, or reduction of risk of harm or hospital, nursing home, or other institutional care. Homemaker services would include assistance with personal care; home management; completion of simple household tasks; nutrition, including menu planning and meal preparation; consumer education; and hygiene education. Homemaker services may include assistance with IADLs, such as: Light housekeeping; laundering; meal preparation; necessary services to maintain a safe and sanitary environment in the areas of the home used by the individual; and services essential to the comfort and cleanliness of the individual and ensuring individual safety. We would require that homemaker services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

Home health aide services would mean personal care and related support services to an individual in the home or other place of residence. Home health aide services may include assistance with ADLs such as: Bathing; toileting; eating; dressing; aid in ambulating or transfers; active and passive exercises; assistance with medical equipment; and routine health monitoring. We would also provide that home health aide services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

Homemaker and home health aide services that are provided outside the beneficiary's residence, such as services related to grocery shopping, would not be covered, because the definition of home care is limited to those services provided in the child's home or other place of residence. Activities that have no therapeutic value or are not medical in nature also would not be covered. These activities include assisting an individual with personal correspondence or paying bills. For this reason, we define ''health-related services'' to include only those ADLs and IADLs with therapeutic value.

As with all services under section 1803, however, only those health-related services that are medical in nature and provided by an approved health care provider are covered by VA. Health-related services generally are delivered by different types of providers including personal attendants, custodial care providers, or companion services providers, and there may be instances in which these service providers are not ''approved health care providers'' as that term is defined by statute and regulation. As discussed in further detail below, we propose to require preauthorization for homemaker services, which is a subset of health-related services, and would be a newly defined service provided under existing statutory authority. VA already has an established review and payment process in place for home health aide services. Preauthorization for certain health care services is covered in § 17.902 and is discussed below. We believe that these requirements appropriately balance the needs of the beneficiaries served through this program and the statutory and regulatory requirements that any services provided through the program must be medical in nature and provided by an approved health care provider.

As noted above, home care is furnished to a child in the child's home or other place of residence. The term ''other place of residence'' is not further defined. In general, we believe this term applies to those instances in which the child may need a level of assistance that is not available in the home, but a higher level of care such as admission to a nursing home is not needed. We propose to define ''other place of residence'' to include assisted living facilities or residential group homes, both of which provide an intermediate level of assistance. We note that, while VA would provide home care services in an assisted living facility or residential group home, VA is not authorized to pay for a child to stay in either an assisted living facility or residential group home. The types of alternatives to home care that VA may provide under section 1803 are nursing home care, hospital care, and respite care.

We would also add a definition of ''long-term care'' to clarify the types of long-term care VA is authorized to provide under these programs. The term ''long-term care'' is not currently defined, and VA is frequently asked what types of long-term care VA is authorized to provide. Generally, ''long-term care'' encompasses a variety of services that include medical and non-medical care to people who have a chronic illness or disability. However, VA is authorized to provide only those types of long-term care that constitute ''health care'' as defined in 38 U.S.C. 1803(c)(1)(A). The three categories of health care VA has determined would be considered long-term care are home care, nursing home care, and respite care. We propose to define the term ''long-term care'' consistent with that determination. We would also amend the definition of ''health care'' to include long-term care.

In addition to the definitional clarifications proposed above, we propose to amend § 17.902, which sets forth the list of services and benefits for which preauthorization by VA is required. Preauthorization allows VA to ensure that health care services are provided by approved health care providers, prescribed and medically necessary, and provided at a reasonable cost. Requiring prior approval also limits the likelihood that beneficiaries will incur liability for non-reimbursable expenses. In selecting those services that require preauthorization, we focused on those services where there is likely to be a high cost and some question regarding whether a particular health care service meets the requirements of §§ 17.900 and 17.901.

Preauthorization is currently required for all mental health services. We would amend § 17.902(a) to provide that preauthorization is required only for outpatient mental health services in excess of 23 visits in a calendar year. We believe this change would assist beneficiaries by providing them with greater flexibility in obtaining needed mental health services. The proposed change would also align the preauthorization requirements for these programs with CHAMPVA, which does not require preauthorization for inpatient mental health services and requires preauthorization for outpatient mental health services only after the 23rd visit in a calendar year. CHAMPVA likewise covers non-veteran beneficiaries, and following the CHAMPVA standard here would ensure consistency. In addition, this proposed change would decrease the administrative burden for beneficiaries and would ensure that there is no delay in initiating necessary outpatient mental health services.

We also propose to add homemaker services to the list of services that require preauthorization. Both homemaker services and home health aide services are defined as health-related services. We would not require preauthorization for home health aide services, because VA has an existing

payment schedule and an established review process for these services. However, we would require preauthorization for homemaker services, because VA's authority to provide homemaker services is limited by type and scope. VA believes that requiring preauthorization for homemaker services would mitigate the possibility of beneficiaries receiving certain homemaker services that would not be covered by VA because the service was provided outside the individual's home or other place of residence, or the service had no therapeutic value.

As we noted above, day health care is an element of both outpatient care and respite care. VA already provides day health care to eligible beneficiaries as part of respite care, but it would now also be included as an element of outpatient care. Respite care, as a distinct class of services, does not require preauthorization. However, we would require preauthorization for day health care as part of outpatient care only to ensure that the day health care being claimed is a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, and nutrition, and that the service is obtained at a reasonable cost. Preauthorization would still be required for dental services; substance abuse treatment; training; transplantation services; and travel (other than mileage at the General Services Administration rate for privately owned automobiles).

Current § 17.902(a) states that authorization will only be given in spina bifida cases where there is a demonstrated medical need. ''Medically necessary'' is a more easily understood and more commonly used term than is ''demonstrated medical need'' and we propose to amend this paragraph to reflect the more commonly used term.

Payment for health care services is addressed in § 17.903(a)(1). The current rule states that payment for health care services will be determined using the same payment methodologies as provided for under CHAMPVA regulations. VA recognizes that services covered by CHAMPVA change periodically, and there may be instances in which CHAMPVA does not have a payment methodology for all health care services available under §§ 17.900 through 17.905. For instance, homemaker services are excluded from CHAMPVA coverage at 38 CFR 17.272(a)(55) but may be covered as health-related services under § 17.900. To address this, we propose to amend this paragraph to state that payment for services or benefits covered by §§ 17.900 through 17.905 but not covered by CHAMPVA regulations will be determined using the same or similar payment methodologies applied by VA for the equivalent services or benefits provided to veterans. This may include negotiating a rate with the provider or using a national average or the Medicare rate.

We would make a technical edit to the definition of ''approved health care provider'' found in § 17.900. The current definition of ''approved health care provider'' includes health care providers currently approved by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). In 2007, JCAHO changed its name to The Joint Commission and we would amend this definition to reflect that change.

Finally, we address the Office of Management and Budget (OMB) control number referenced in §§ 17.902 through 17.904. OMB had approved information collection for purposes of the Paperwork Reduction Act under OMB control number 2900–0578 for provision of health care, preauthorization, payment, review, and appeals. In 2010, OMB determined that information collection for the Spina Bifida Health Care Benefits program should be combined with a parallel information collection approved for CHAMPVA. This combined information collection was approved under OMB control number 2900–0219. We would make a technical edit to reflect the correct OMB control number.

**Effect of Rulemaking**

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

**Paperwork Reduction Act**

This proposed rule includes provisions constituting a modification to a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that requires approval by OMB. Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking to OMB for review.

OMB assigns control numbers to collections of information it approves. VA 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. Proposed § 17.902 contains a collection of information under the Paperwork Reduction Act of 1995. If OMB does not approve the modification as requested, VA will immediately remove the provisions containing a collection of information or take such other action as is directed by OMB.

Comments on the modification to the collection[s] of information contained in this proposed rule should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies sent by mail or hand delivery to the Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or through *www.Regulations.gov.* Comments should indicate that they are submitted in response to ''RIN 2900–AP09—Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans—Covered Birth Defects and Spina Bifida.''

OMB is required to make a decision concerning the modification to the collection of information contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the proposed rule.

VA considers comments by the public on proposed collections of information in—

- Evaluating whether the proposed collections of information are necessary for the proper performance of the functions of VA, including whether the information will have practical utility;
- Evaluating the accuracy of VA's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections 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.

The modifications to the collection of information contained in 38 CFR 17.902 are described immediately following this paragraph, under their respective titles.

*Title:* Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans—Covered Birth Defects and Spina Bifida.

*Summary of collection of information:* Section 17.902(a) states that preauthorization from VA is required for certain services or benefits under §§ 17.900 through 17.905. VA is modifying the preauthorization requirement for mental health services to only require preauthorization for outpatient mental health services in excess of 23 visits in a calendar year. VA also adds day health care provided as outpatient care and homemaker services to the list of services or benefits that must receive preauthorization.

*Description of the need for information and proposed use of information:* The information collected is needed to carry out the health care programs for certain children of Korea and/or Vietnam veterans authorized under 38 U.S.C. chapter 18, as amended by section 401, Public Law 106–419 and section 102, Public Law 108–183. VA's medical regulations 38 CFR part 17 (17.900 through 17.905) establish regulations regarding provisions of health care for certain children of Korea and Vietnam veterans and women Vietnam veterans' children born with spina bifida and certain other covered birth defects. These regulations specify this information to be included in requests for preauthorization and claims from approved health care providers and eligible Veterans.

*Description of likely respondents:* Veterans and eligible family members seeking reimbursement for claims associated with spina bifida and certain other covered birth defects.

*Estimated number of respondents per year:* 12.

*Estimated frequency of responses:* 1 time per year.

*Estimated average burden per response:* 10 minutes.

*Estimated total annual reporting and recordkeeping burden:* 2 hours.

**Regulatory Flexibility Act**

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

**Executive Orders 12866 and 13563**

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for VA Regulations Published From FY 2004 to FYTD.

**Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

**Catalog of Federal Domestic Assistance**

There are no Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document.

**Signing Authority**

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on April 2, 2015, for publication.

**List of Subjects in 38 CFR Part 17**

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: May 11, 2015.

**William F. Russo,**

*Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.*

For the reasons stated in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 17 as follows:

## PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.900 by:

■ a. In the definition of ''Approved health care provider'' removing ''Joint Commission on Accreditation of Health Care Organizations (JCAHO)'' from the first sentence and adding, in its place, ''The Joint Commission'';

■ b. Adding in alphabetical order a definition of ''Day health care'';

■ c. In the definition of ''Health care'' adding ''long-term care,'' to the first sentence immediately after ''hospital care,'';

■ d. Adding in alphabetical order definitions of ''Health-related services'',

''Home health aide services'',''Homemaker services'', ''Long-term care'', and ''Other place of residence'';

■ e. In the definition of ''Outpatient care'' adding ''day health care and'' immediately after the word ''including''; and

■ f. Revising the definition of ''Respite care''.

The additions and revision read as follows:

**§ 17.900 Definitions.**

* * * * *

*Day health care* means a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care may be provided as a component of outpatient care or respite care.

* * * * *

*Health-related services* means homemaker or home health aide services furnished in the individual's home or other place of residence to the extent that those services provide assistance with Activities of Daily Living and Instrumental Activities of Daily Living that have therapeutic value.

* * * * *

*Home health aide services* is a component of health-related services providing personal care and related support services to an individual in the home or other place of residence. Home health aide services may include assistance with Activities of Daily Living such as: Bathing; toileting; eating; dressing; aid in ambulating or transfers; active and passive exercises; assistance with medical equipment; and routine health monitoring. Home health aide services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

*Homemaker services* is a component of health-related services encompassing certain activities that help to maintain a safe, healthy environment for an individual in the home or other place of residence. Such services contribute to the prevention, delay, or reduction of risk of harm or hospital, nursing home, or other institutional care. Homemaker services include assistance with personal care; home management; completion of simple household tasks; nutrition, including menu planning and meal preparation; consumer education; and hygiene education. Homemaker services may include assistance with Instrumental Activities of Daily Living, such as: Light housekeeping; laundering; meal preparation; necessary services to maintain a safe and sanitary environment in the areas of the home used by the individual; and services essential to the comfort and cleanliness of the individual and ensuring individual safety. Homemaker services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

* * * * *

*Long-term care* means home care, nursing home care, and respite care.

* * * * *

*Other place of residence* includes an assisted living facility or residential group home.

* * * * *

*Respite care* means care, including day health care, furnished by an approved health care provider on an intermittent basis for a limited period to an individual who resides primarily in a private residence when such care will help the individual continue residing in such private residence.

* * * * *

■ 3. Amend § 17.902 by:

■ a. Revising the first three sentences of paragraph (a); and

■ b. At the end of the section, removing ''2900–0578'' from the notice of the Office of Management and Budget control number and adding, in its place, ''2900–0219''.

The revisions read as follows:

**§ 17.902 Preauthorization.**

(a) Preauthorization from VA is required for the following services or benefits under §§ 17.900 through 17.905: Rental or purchase of durable medical equipment with a total rental or purchase price in excess of $300, respectively, day health care provided as outpatient care; dental services; homemaker services; outpatient mental health services in excess of 23 visits in a calendar year; substance abuse treatment; training; transplantation services; and travel (other than mileage at the General Services Administration rate for privately owned automobiles). Authorization will only be given in spina bifida cases where it is demonstrated that the care is medically necessary. In cases of other covered birth defects, authorization will only be given where it is demonstrated that the care is medically necessary and related to the covered birth defects. * * *

* * * * *

■ 4. Amend § 17.903 by:

■ a. In paragraph (a)(1), adding a second sentence; and

■ b. At the end of the section, removing ''2900–0578'' from the notice of the Office of Management and Budget control number and adding, in its place, ''2900–0219''.

The addition reads as follows:

**§ 17.903 Payment.**

(a)(1) * * * For those services or benefits covered by §§ 17.900 through 17.905 but not covered by CHAMPVA we will use payment methodologies the same or similar to those used for equivalent services or benefits provided to veterans.

* * * * *

**§ 17.904 [Amended]**

■ 5. Amending § 17.904 by, at the end of the section, removing ''2900–0578'' from the notice of the Office of Management and Budget control number and adding, in its place, ''2900–0219''.

[FR Doc. 2015–11718 Filed 5–14–15; 8:45 am]

BILLING CODE 8320–01–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[EPA–HQ–SFUND–1986–0005; FRL–9927–73–Region 5]**

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Deletion of the Burrows Sanitation Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule; notice of intent.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent to Delete the Burrows Sanitation Superfund Site located in Hartford Township, Van Buren County, Michigan from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Michigan, through the Michigan Department of Environment Quality (MDEQ), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** Comments must be received by June 15, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1986–0005, by one of the following methods:

- *http://www.regulations.gov:* Follow online instructions for submitting comments.
- Email: Jeffrey Gore, Remedial Project Manager, at *gore.jeffrey@epa.gov* or Cheryl Allen, Community Involvement Coordinator, at *allen.cheryl@epa.gov*.
- Fax: Gladys Beard, NPL Deletion Process Manager, at (312) 697–2077.
- Mail: Jeffrey Gore, Remedial Project Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6552, or Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–6196 or (800) 621–8431.
- Hand delivery: Cheryl Allen, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding federal holidays.

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–SFUND–1986–0005. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be 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 the hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at:

- U.S. Environmental Protection Agency—Region 5, 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 353–1063, Hours: Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding federal holidays.
- Harford Public Library, 15 Franklin Street, Hartford, MI 49057, Phone: (269) 621–3408, Hours: Monday through Wednesday, 10:00 a.m. to 7:00 p.m., Thursday and Friday 10:00 a.m. to 5:00 p.m., Saturday 10:00 a.m. to 5:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Gore, Remedial Project Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6552, or *gore.jeffrey@epa.gov*.

**SUPPLEMENTARY INFORMATION:** In the ''Rules and Regulations'' section of today's **Federal Register,** we are publishing a direct final Notice of Deletion of the Burrows Sanitation Superfund Site without prior Notice of Intent to Delete because we view this as a noncontroversial decision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

**List of Subjects in 40 CFR Part 300**

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

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: April 30, 2015.

**Susan Hedman,**

*Regional Administrator, Region 5.*

[FR Doc. 2015–11800 Filed 5–14–15; 8:45 am]

BILLING CODE 6560–50–P

# Notices

Federal Register
Vol. 80, No. 94
Friday, May 15, 2015

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

### Food and Nutrition Service

### Agency Information Collection Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices

**AGENCY:** Food and Nutrition Service, USDA.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act (PRA) of 1995, this Notice invites the general public and other public agencies to comment on proposed information collections. This collection is a revision of currently approved burden for the applications, periodic reporting, and notices burden calculations for the Supplemental Nutrition Assistance Program (SNAP). The revision also modifies the net estimates for PRA burden associated with proposed rule ''Supplemental Nutrition Assistance Program (SNAP): Eligibility, Certification, and Employment and Training Provisions'' published on May 4, 2011 at 76 FR 25413.

**DATES:** Written comments must be submitted on or before July 14, 2015 to be assured consideration.

**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 will have 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; and (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.

Send comments to Sasha Gersten-Paal, Chief, Certification Policy Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 812, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Sasha Gersten-Paal at 703–305–2486. Comments will also be accepted through the Federal eRulemaking 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 during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at the office of the Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302, Room 800.

All comments will be summarized and included in the request for Office of Management and Budget approval of the information collection. All comments will become a matter of public record.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Sasha Gersten-Paal at 703–305–2507.

**SUPPLEMENTARY INFORMATION:**

*Title:* Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices.

*OMB Number:* 0584–0064.

*Form Number:* None.

*Expiration Date:* April 30, 2016.

*Type of Request:* Revision of an existing collection.

*Abstract:* This notice revises the Applications, Periodic Reporting, and Notices burden for the Supplemental Nutrition Assistance Program (SNAP). The Federal procedures for implementing the application and certification procedures in the Act are in Parts 271, 272, and 273 of the Title 7 of the Code of **Federal Register**. Part 271 contains general information and definitions, Part 272 contains requirements for participating State agencies, and Part 273 contains procedures for the certification of eligible households.

After careful review and consideration of the burden inventory under OMB No. 0584–0064, FNS has determined the burden baseline does not accurately reflect the burden activities or hours required by the SNAP under this collection. We have corrected the burden inventory baseline to establish burden estimates under OMB No. 0584–0064 that more accurately reflect the information collection burdens of SNAP's existing application and recertification process. An overview is provided in this notice and additional details are available in the docket at [Placeholder].

Section 3502.2 of the PRA defines burden as ''time, effort, or financial resources expended by a person to generate, maintain, or provide information to or for a Federal agency.''

In keeping with the PRA definition of burden, we created sub-activity categories that allowed for the inclusion of time and effort expended on behalf of households and State agencies and revised the time estimates. Note that no changes have been made to the existing reporting and recordkeeping requirements. The change in burden is due to formulating more accurate burden estimates associated with the existing requirements.

The following tables compare the time estimates for activities contained in the currently approved information collection with the revised burden baseline activities.

| Time estimates established in the currently approved OMB No. 0584–0064 | | Activities and time estimates for revising burden baseline for OMB No. 0584–0064 | |
|---|---|---|---|
| State agency | | State agency | |
| Information collection activities | Time estimate (minutes) | Information collection activities | Time estimate (minutes) |
| Initial Application | 19 | Initial Application: | 19 |
| | | Interview | 30 |
| | | Verification | 24 |
| Recertification Application | 19 | Recertification Application: | 15 |
| | | Interview | 20 |
| | | Verification | 10 |
| Reports: | | Periodic Reports: | |
| Monthly Reports | 11 | Monthly Reports | 7 |
| Quarterly Reports | 12 | Quarterly Reports | 8 |
| Simplified Reports | 11 | Simplified Reports | 11 |
| Change Reports | 11 | Change Report | 11 |
| Notices: | | Notices: | |
| Notice of Eligibility or Denial | 2 | Notice of Eligibility or Denial | 2 |
| Notice of Missing or Incomplete Report | 2 | Notice of Missing or Incomplete Report | 2 |
| Notice of Missed Interview | 1 | Notice of Missed Interviews | 1 |
| Notice of Expiration | 2 | Notice of Expiration | 2 |
| Notice of Adverse Action | 2 | Notice of Adverse Action | 2 |
| Adequate Notice for Monthly Reports | 2 | Adequate Notice | 2 |
| Request for Contact | 2 | Request for Contact | 2 |
| Transition Notice | 0 | Transitional notice | 0 |

| Time estimates established in the currently approved OMB No. 0584–0064 | | Activities and time estimates for revising burden baseline for OMB No. 0584–0064 | |
|---|---|---|---|
| Households | | Households | |
| Information collection activities | Time estimate (minutes) | Information collection activities | Time estimate (minutes) |
| Initial Application | 19 | Initial SNAP Application: | 19 |
| | | Interview | 30 |
| | | Travel time—In office interview | 120 |
| | | Verification | 24 |
| Recertification Application | 19 | SNAP Recertification Application: | 15 |
| | | Interview | 20 |
| | | Travel time—In office interview | 120 |
| | | Verification | 10 |
| Reports: | | Periodic Reports: | |
| Monthly Reports | 7 | Monthly Reports | 7 |
| Quarterly Reports | 8 | Quarterly Reports | 8 |
| Simplified Reports | 8 | Simplified or Periodic Reports | 10 |
| Change Report | 5 | Change Reports | 10 |
| Notices: | | Notices: | |
| Notice of Missed Interview | 1 | Notice of Missed Interviews | 1 |
| Notice of Adverse Action | 1 | Notice of Adverse Action | 1 |
| Adequate Notice | 1 | Adequate Notice | 1 |
| Request for Contact | 2 | Request for Contact | 2 |

Additionally, the burden estimates included in this collection account for the burden applicable to each SNAP applicant. The estimated number of applicants has increased from the prior estimate of approximately 11 million applicants to over 14.5 million applicants in Fiscal Year 2014.

The net impact to the burden is summarized below.

**Summary of Estimated Burden**

*Affected Public:* State and local government agencies administering SNAP and Individuals/Households.

*Estimated Number of Respondents:* 14,619,642.

*Estimated Number of Responses per Respondent:* 45.04.

*Estimated Total Number of Annual Responses:* 658,539,827.

*Estimated Hours per Response:* .1795.

*Estimated Total Annual Burden Hours:* 118,221,440.

*Current Burden Inventory:* 24,897,947.

*Net Increase:* 93,323,493.

Dated: May 4, 2015.

**Audrey Rowe,**

*Administrator, Food and Nutrition Service.*

[FR Doc. 2015–11752 Filed 5–14–15; 8:45 am]

BILLING CODE 3410–30–P

## DEPARTMENT OF AGRICULTURE

### Rural Business-Cooperative Service

### Inviting Applications for Value-Added Producer Grants

**AGENCY:** Rural Business-Cooperative Service, USDA.

**ACTION:** Notice, Correction.

**SUMMARY:** The Rural Business-Cooperative Service published a Notice in the **Federal Register** on Friday, May 8, 2015 (80 FR 26528), inviting applications for the Value Added Producer Grant Program. The document contained an incorrect date for

submitting paper applications, as well as an incorrect contact telephone number.

**FOR FURTHER INFORMATION CONTACT:** Grants Division, Cooperative Programs, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., MS 3253, Room 4008—South, Washington, DC 20250–3253, or call 202–690–1374.

**Correction**

In the Notice [FR Doc 2015–10040], published May 8, 2015 (80 FR 26528), column 2, under **FOR FURTHER INFORMATION CONTACT** should read ''Grants Division, Cooperative Programs, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., MS 3253, Room 4208—South, Washington, DC 20250–3253, or call 202–690–1374.''

In the Notice, [FR Doc 2015–10040] published May 8, 2015 (80 FR 26530), column 3, under ''4. Submission Dates and Times.'' The first sentence under ''Explanation of Deadlines'' should read ''Paper applications must be postmarked and mailed, shipped, or sent overnight by July 7, 2015.''

In the Notice, [FR Doc 2015–10040] published May 8, 2015 (80 FR 26534), column 1, under ''G. Agency Contacts,'' The fourth sentence should read ''You may also contact National Office staff: Tracey Kennedy, VAPG Program Lead, *tracey.kennedy@wdc.usda.gov,* or Shantelle Gordon, *shantelle.gordon@wdc.usda.gov,* or call the main line at 202–690–1374.''

Dated: May 11, 2015.

**Chad Parker,**

*Acting Administrator, Rural Business-Cooperative Service.*

[FR Doc. 2015–11742 Filed 5–14–15; 8:45 am]

**BILLING CODE 3410–XY–P**

## DEPARTMENT OF AGRICULTURE

### Rural Housing Service

### Notice of Solicitation of Applications for the Rural Community Development Initiative for Fiscal Year 2015

**AGENCY:** Rural Housing Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Rural Housing Service (RHS), an agency within the USDA Rural Development mission area herein referred to as the Agency announces the acceptance of applications under the Rural Community Development Initiative (RCDI) program. Applicants must provide matching funds in an amount at least equal to the Federal grant. These grants will be made to qualified intermediary organizations that will provide financial and technical assistance to recipients to develop their capacity and ability to undertake projects related to housing, community facilities, or community and economic development that will support the community.

This Notice lists the information needed to submit an application for these funds. This Notice contains revised evaluation criteria that are streamlined, in order to enhance program efficiency and delivery.

**DATES:** The deadline for receipt of an application is 4 p.m. local time, August 13, 2015. The application date and time are firm. The Agency will not consider any application received after the deadline. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX) and postage due applications will not be accepted.

**ADDRESSES:** Entities wishing to apply for assistance may download the application documents and requirements delineated in this Notice from the RCDI Web site: *http://www.rd.usda.gov/programs-services/rural-community-development-initiative-grants.*

Application information for electronic submissions may be found at *http://www.grants.gov.*

Applicants may also request paper application packages from the Rural Development office in their state. A list of Rural Development State offices can be found via *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf.*

**FOR FURTHER INFORMATION CONTACT:** The Rural Development office for the state in which the applicant is located. A list of Rural Development State Office contacts is provided at the following link: *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf.*

**Paperwork Reduction Act**

The paperwork burden has been cleared by the Office of Management and Budget (OMB) under OMB Control Number 0575–0180.

**SUPPLEMENTARY INFORMATION:**

**Overview**

*Federal Agency:* Rural Housing Service.

*Funding Opportunity Title:* Rural Community Development Initiative.

*Announcement Type:* Initial Announcement.

*Catalog of Federal Domestic Assistance (CFDA) Number: 10.446.*

*Dates:* The deadline for receipt of an application is 4 p.m. local time, August 13, 2015. The application date and time are firm. The Agency will not consider any application received after the deadline. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX) and postage due applications will not be accepted.

**A. Program Description**

Congress first authorized the RCDI in 1999 (Pub. L. 106–78, which was amended most recently by The Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235)). The RCDI was authorized to develop the capacity and ability of qualified private, nonprofit community-based housing and community development organizations, low-income rural communities, and federally recognized Native American Tribes to undertake projects related to housing, community facilities, or community and economic development in rural areas. Strengthening the recipient's capacity in these areas will benefit the communities they serve. The RCDI structure requires the intermediary (grantee) to provide a program of financial and technical assistance to recipients. The recipients will, in turn, provide programs to their communities (beneficiaries).

Of particular note this year, the Agency is encouraging applications for projects based in or servicing high poverty areas. This emphasis will support Rural Development's (RD) mission of improving the quality of life for rural Americans and commitment to directing resources to those who most need them.

**B. Federal Award Information**

Congress, in The Continuing and Further Continuing Appropriations Act, 2015 (Pub.L. 113–235), appropriated $4,000,000 in FY 2015 for the RCDI program. The amount of funding received in the FY 2015 Appropriations Act can also be found at the following link: *http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas#nosa.*

Qualified private, nonprofit and public (including tribal) intermediary organizations proposing to carry out financial and technical assistance programs will be eligible to receive the grant funding.

The intermediary will be required to provide matching funds in an amount at least equal to the RCDI grant.

A grant will be the type of assistance instrument awarded to successful applications.

The respective minimum and maximum grant amount per intermediary is $50,000 and $250,000.

Grant funds must be utilized within 3 years from date of the award.

A grantee that has an outstanding RCDI grant over 3 years old, as of the application due date in this Notice, is not eligible to apply for this round of funding.

The intermediary must provide a program of financial and technical assistance to one or more of the following: A private, nonprofit community-based housing and development organization, a low-income rural community or a federally recognized tribe.

**C. Eligibility Information**

Applicants must meet all of the following eligibility requirements by the application deadline. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be evaluated further, and will not receive a Federal award.

*1. Eligible Applicants*

(a) Qualified private, nonprofit, (including faith-based and community organizations and philanthropic foundations), in accordance with 7 CFR part 16, and public (including tribal) intermediary organizations are eligible applicants. Definitions that describe eligible organizations and other key terms are listed below.

(b) The recipient must be a nonprofit community-based housing and development organization, low-income rural community, or federally recognized tribe based on the RCDI definitions of these groups.

(c) Private nonprofit, faith or community-based organizations must provide a certificate of incorporation and good standing from the Secretary of the State of incorporation, or other similar and valid documentation of nonprofit status. For low-income rural community recipients, the Agency requires evidence that the entity is a public body and census data verifying that the median household income of the community where the office receiving the financial and technical assistance is located is at, or below, 80 percent of the State or national median household income, whichever is higher. For federally recognized tribes, the Agency needs the page listing their name from the current **Federal Register** list of tribal entities recognized and eligible for funding services (see the definition of federally recognized tribes in this Notice for details on this list).

(d) Any corporation (1) that has been convicted of a felony criminal violation under any Federal law within the past 24 months or (2) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; is not eligible for financial assistance provided with funds appropriated by the Consolidated and Further Continuing Appropriations Act, 2015, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

*2. Cost Sharing or Matching*

There is a matching requirement of at least equal to the amount of the grant. If this matching funds requirement is not met, the application will be deemed ineligible. See section D, Application and Submission Information, for required pre-award and post award matching funds documentation submission.

The intermediary must provide matching funds at least equal to the amount of the grant. Verification of matching funds must be submitted with the application. Matching funds must be committed for a period equal to the grant performance period. The intermediary will be required to provide matching funds in an amount at least equal to the RCDI grant. In-kind contributions such as salaries, donated time and effort, real and nonexpendable personal property and goods and services cannot be used as matching funds.

Matching funds are cash or confirmed funding commitments and must be at least equal to the grant amount and committed for a period of not less than the grant performance period. These funds can only be used for eligible RCDI activities. Matching funds must be used to support the overall purpose of the RCDI program.

In-kind contributions such as salaries, donated time and effort, real and nonexpendable personal property and goods and services cannot be used as matching funds.

Grant funds and matching funds must be used in equal proportions. This does not mean funds have to be used equally by line item.

The request for advance or reimbursement and supporting documentation must show that RCDI fund usage does not exceed the cumulative amount of matching funds used.

Grant funds will be disbursed pursuant to relevant provisions of 2 CFR parts 200 and 400. Verification of matching funds must be submitted with the application. See Section D, other program requirements, for matching funds documentation and pre-award requirements.

The intermediary is responsible for demonstrating that matching funds are available, and committed for a period of not less than the grant performance period to the RCDI proposal. Matching funds may be provided by the intermediary or a third party. Other Federal funds may be used as matching funds if authorized by statute and the purpose of the funds is an eligible RCDI purpose.

RCDI funds will be disbursed on an advance or reimbursement basis. Matching funds cannot be expended prior to execution of the RCDI Grant Agreement.

*3. Other Program Requirements*

(a) The recipient and beneficiary, but not the intermediary, must be located in an eligible rural area. The physical location of the recipient's office that will be receiving the financial and technical assistance must be in an eligible rural area. If the recipient is a low-income community, the median household income of the area where the office is located must be at or below 80 percent of the State or national median household income, whichever is higher. The applicable Rural Development State Office can assist in determining the eligibility of an area.

A listing of Rural Development State Office contacts can be found at the following link: *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf.* A map showing eligible rural areas can be found at the following link: *http://eligibility.sc.egov.usda.gov/eligibility/welcomeAction.do?pageAction=RBSmenu&NavKey=property@13.*

(b) RCDI grantees that have an outstanding grant over 3 years old, as of the application due date in this Notice, will not be eligible to apply for this round of funding. Grant and matching funds must be utilized in a timely manner to ensure that the goals and objectives of the program are met.

(c) Individuals cannot be recipients.

(d) The intermediary must provide a program of financial and technical assistance to the recipient.

(e) The intermediary organization must have been legally organized for a minimum of 3 years and have at least 3 years prior experience working with private nonprofit community-based housing and development organizations, low-income rural communities, or tribal organizations in the areas of housing, community facilities, or community and economic development.

(f) Proposals must be structured to utilize the grant funds within 3 years from the date of the award.

(g) Each applicant, whether singularly or jointly, may only submit one application for RCDI funds under this Notice. This restriction does not preclude the applicant from providing matching funds for other applications.

(h) Recipients can benefit from more than one RCDI application; however, after grant selections are made, the recipient can only benefit from multiple RCDI grants if the type of financial and technical assistance the recipient will receive is not duplicative. The services described in multiple RCDI grant applications must have separate and identifiable accounts for compliance purposes.

(i) The intermediary and the recipient cannot be the same entity. The recipient can be a related entity to the intermediary, if it meets the definition of a recipient, provided the relationship does not create a Conflict of Interest that cannot be resolved to Rural Development's satisfaction.

(j) If the recipient is a low-income rural community, identify the unit of government to which the financial and technical assistance will be provided, *e.g.,* town council or village board. The financial and technical assistance must be provided to the organized unit of government representing that community, not the community at large.

*4. Eligible Grant Purposes*

Fund uses must be consistent with the RCDI purpose. A nonexclusive list of eligible grant uses includes the following:

(a) Provide technical assistance to develop recipients' capacity and ability to undertake projects related to housing, community facilities, or community and economic development, *e.g.,* the intermediary hires a staff person to provide technical assistance to the recipient or the recipient hires a staff person, under the supervision of the intermediary, to carry out the technical assistance provided by the intermediary.

(b) Develop the capacity of recipients to conduct community development programs, *e.g.,* homeownership education or training for business entrepreneurs.

(c) Develop the capacity of recipients to conduct development initiatives, *e.g.,* programs that support micro-enterprise and sustainable development.

(d) Develop the capacity of recipients to increase their leveraging ability and access to alternative funding sources by providing training and staffing.

(e) Develop the capacity of recipients to provide the technical assistance component for essential community facilities projects.

(f) Assist recipients in completing pre-development requirements for housing, community facilities, or community and economic development projects by providing resources for professional services, *e.g.,* architectural, engineering, or legal.

(g) Improve recipient's organizational capacity by providing training and resource material on developing strategic plans, board operations, management, financial systems, and information technology.

(h) Purchase of computers, software, and printers, limited to $10,000 per award, at the recipient level when directly related to the technical assistance program being undertaken by the intermediary.

(i) Provide funds to recipients for training-related travel costs and training expenses related to RCDI.

*5. Ineligible Fund Uses*

The following is a list of ineligible grant uses:

(a) Pass-through grants, and any funds provided to the recipient in a lump sum that are not reimbursements.

(b) Funding a revolving loan fund (RLF).

(c) Construction (in any form).

(d) Salaries for positions involved in construction, renovations, rehabilitation, and any oversight of these types of activities.

(e) Intermediary preparation of strategic plans for recipients.

(f) Funding prostitution, gambling, or any illegal activities.

(g) Grants to individuals.

(h) Funding a grant where there may be a conflict of interest, or an appearance of a conflict of interest, involving any action by the Agency.

(i) Paying obligations incurred before the beginning date without prior Agency approval or after the ending date of the grant agreement.

(j) Purchasing real estate.

(k) Improvement or renovation of the grantee's, or recipient's office space or for the repair or maintenance of privately owned vehicles.

(l) Any purpose prohibited in 2 CFR part 200 or 400.

(m) Using funds for recipient's general operating costs.

(n) Using grant or matching funds for Individual Development Accounts.

(o) Purchasing vehicles.

*6. Program Examples and Restrictions*

The following are examples of eligible and ineligible purposes under the RCDI program. (These examples are illustrative and are not meant to limit the activities proposed in the application. Activities that meet the objectives of the RCDI program and meet the criteria outlined in this Notice will be considered eligible.)

(a) The intermediary must work directly with the recipient, not the ultimate beneficiaries. As an example:

The intermediary provides training to the recipient on how to conduct homeownership education classes. The recipient then provides ongoing homeownership education to the residents of the community—the ultimate beneficiaries. This ''train the trainer'' concept fully meets the intent of this initiative. The intermediary is providing technical assistance that will build the recipient's capacity by enabling them to conduct homeownership education classes for the public.

This is an eligible purpose. However, if the intermediary directly provided homeownership education classes to individuals in the recipient's service area, this would not be an eligible purpose because the recipient would be bypassed.

(b) If the intermediary is working with a low-income community as the recipient, the intermediary must provide the technical assistance to the entity that represents the low-income community and is identified in the application. Examples of entities representing a low-income community are a village board or a town council.

If the intermediary provides technical assistance to the Board of the low-income community on how to establish a cooperative, this would be an eligible purpose. However, if the intermediary works directly with individuals from the community to establish the cooperative, this is not an eligible purpose.

The recipient's capacity is built by learning skills that will enable them to support sustainable economic development in their communities on an ongoing basis.

(c) The intermediary may provide technical assistance to the recipient on how to create and operate a revolving loan fund. The intermediary may not

monitor or operate the revolving loan fund. RCDI funds, including matching funds, cannot be used to fund revolving loan funds.

(d) The intermediary may work with recipients in building their capacity to provide planning and leadership development training. The recipients of this training would be expected to assume leadership roles in the development and execution of regional strategic plans. The intermediary would work with multiple recipients in helping communities recognize their connections to the greater regional and national economies.

(e) The intermediary could provide training and technical assistance to the recipients on developing emergency shelter and feeding, short-term housing, search and rescue, and environmental accident, prevention, and cleanup program plans. For longer term disaster and economic crisis responses, the intermediary could work with the recipients to develop job placement and training programs, and develop coordinated transit systems for displaced workers.

**D. Application and Submission Information**

*1. Address To Request Application Package*

Entities wishing to apply for assistance may download the application documents and requirements delineated in this Notice from the RCDI Web site: *http://www.rd.usda.gov/programs-services/rural-community-development-initiative-grants.*

Application information for electronic submissions may be found at *http://www.grants.gov.*

Applicants may also request paper application packages from the Rural Development office in their state. A list of Rural Development State office contacts can be found via *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf.* You may also obtain a copy by calling 202–205–9685.

*2. Content and Form of Application Submission*

If the applicant is ineligible or the application is incomplete, the Agency will inform the applicant in writing of the decision, reasons therefore, and its appeal rights and no further evaluation of the application will occur.

A complete application for RCDI funds must include the following:

(a) A summary page, double-spaced between items, listing the following: (This information should not be presented in narrative form.)

(1) Applicant's name,

(2) Applicant's address,

(3) Applicant's telephone number,

(4) Name of applicant's contact person and telephone number,

(5) Applicant's fax number,

(6) County where applicant is located,

(7) Congressional district number where applicant is located,

(8) Amount of grant request, and

(9) Number of recipients.

(b) A detailed Table of Contents containing page numbers for each component of the application.

(c) A project overview, no longer than five pages, including the following items, which will also be addressed separately and in detail under ''Building Capacity and Expertise'' of the ''Evaluation Criteria.''

(1) The type of technical assistance to be provided to the recipients and how it will be implemented.

(2) How the capacity and ability of the recipients will be improved.

(3) The overall goals to be accomplished.

(4) The benchmarks to be used to measure the success of the program. Benchmarks should be specific and quantifiable.

(d) Organizational documents, such as a certificate of incorporation and a current good standing certification from the Secretary of State where the applicant is incorporated and other similar and valid documentation of non-profit status, from the intermediary that confirms it has been legally organized for a minimum of 3 years as the applicant entity.

(e) Verification of source and amount of matching funds, *e.g.,* a copy of a bank statement if matching funds are in cash or a copy of the confirmed funding commitment from the funding source.

The verification must show that matching funds are available for the duration of the grant performance period. The verification of matching funds must be submitted with the application or the application will be considered incomplete.

The applicant will be contacted by the Agency prior to grant award to verify that the matching funds provided with the application continue to be available. The applicant will have 15 days from the date contacted to submit verification that matching funds continue to be available.

If the applicant is unable to provide the verification within that timeframe, the application will be considered ineligible. The applicant must maintain bank statements on file or other documentation for a period of at least 3 years after grant closing except that the records shall be retained beyond the 3-year period if audit findings have not been resolved.

(f) The following information for each recipient:

(1) Recipient's entity name,

(2) Complete address (mailing and physical location, if different),

(3) County where located,

(4) Number of Congressional district where recipient is located,

(5) Contact person's name and telephone number, and

(6) Form RD 400–4, ''Assurance Agreement.'' If the Form RD 400–4 is not submitted for a recipient, the recipient will be considered ineligible. No information pertaining to that recipient will be included in the income or population scoring criteria and the requested funding may be adjusted due to the deletion of the recipient.

(g) Submit evidence that each recipient entity is eligible. Documentation must be submitted to verify recipient eligibility. Acceptable documentation varies depending on the type of recipient:

(1) Nonprofits—provide a current valid letter confirming non-profit status from the Secretary of the State of incorporation or the IRS, a current good standing certification from the Secretary of the State of incorporation, or other valid documentation of nonprofit status of each recipient. A nonprofit recipient must provide evidence that it is a valid nonprofit when the intermediary applies for the RCDI grant. Organizations with pending requests for nonprofit designations are not eligible.

(2) Low-income rural community—provide evidence the entity is a public body, and a copy of the 2010 census data to verify the population, and evidence that the median household income is at, or below, 80 percent of either the State or national median household income. We will only accept data and printouts from *http://www.census.gov.*

(3) Federally recognized tribes—provide the page listing their name from the **Federal Register** list of tribal entities published most recently by the Bureau of Indian Affairs. The 2014 list is available at 79 FR 4748–53 and *http://www.bia.gov/cs/groups/public/documents/text/idc006989.*

(h) Each of the ''Evaluation Criteria'' must be addressed specifically and individually by category. Present these criteria in narrative form. Documentation must be limited to three pages per criterion. The ''Population and Income'' criteria for recipient locations can be provided in the form of a list; however, the source of the data must be included on the page(s).

(i) A timeline identifying specific activities and proposed dates for completion.

(j) A detailed project budget that includes the RCDI grant amount and matching funds. This should be a line-item budget, by category. Categories such as salaries, administrative, other, and indirect costs that pertain to the proposed project must be clearly defined. Supporting documentation listing the components of these categories must be included. The budget should be dated: year 1, year 2, year 3, as applicable.

(k) The indirect cost category in the project budget should be used only when a grant applicant has a federally negotiated indirect cost rate. A copy of the current rate agreement must be provided with the application. Non-federal entities that have never received a negotiated indirect cost rate may use the de minimis rate of 10% of modified total direct costs (MTDC).

(l) Form SF–424, ''Application for Federal Assistance.'' (Do not complete Form SF–424A, ''Budget Information.'' A separate line-item budget should be presented as described in No. 13 of this section.)

(m) Form SF–424B, ''Assurances—Non-Construction Programs.''

(n) Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions.''

(o) Form AD–1048, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions.''

(p) Form AD–1049, ''Certification Regarding Drug-Free Workplace Requirements.''

(q) Certification of Non-Lobbying Activities.

(r) Standard Form LLL, ''Disclosure of Lobbying Activities,'' if applicable.

(s) Form RD 400–4, ''Assurance Agreement,'' for the applicant.

(t) Identify and report any association or relationship with Rural Development employees. (A statement acknowledging whether or not a relationship exists is required).

(u) Form AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' if you are a corporation. A corporation is any entity that has filed articles of incorporation in one of the 50 States, the District of Columbia, the Federated States of Micronesia, the Republic of Palau, and the Republic of the Marshall Islands, or the various territories of the United States including American Samoa, Guam, Midway Islands, Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands. Corporations include both for profit and non-profit entities.

*3. Dun and Bradstreet Data Universal Numbering System (DUNS) and System for Awards Management (SAM)*

Grant applicants must obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number and register in the System for Award Management (SAM) prior to submitting a pre-application pursuant to 2 CFR 25.200(b). In addition, an entity applicant must maintain registration in SAM at all times during which it has an active Federal award or an application or plan under construction by the Agency. Similarly, all recipients of Federal financial assistance are required to report information about first-tier subawards and executive compensation in accordance to 2 CFR part 170. So long as an entity applicant does not have an exception under 2 CFR 170.110(b), the applicant must have the necessary processes and systems in place to comply with the reporting requirements should the applicant receive funding. See 2 CFR 170.200(b).

An applicant, unless excepted under 2 CFR 25.110(b), (c), or (d), is required to:

(a) Be registered in SAM before submitting its application;

(b) Provide a valid DUNS number in its application; and

(c) Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The Federal awarding agency may not make a federal award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

As required by the Office of Management and Budget (OMB), all grant applications must provide a DUNS number when applying for Federal grants, on or after October 1, 2003. Organizations can receive a DUNS number at no cost by calling the dedicated toll-free number at 1–866–705–5711 or via Internet at *http://fedgov.dnb.com/webform.* Additional information concerning this requirement can be obtained on the Grants.gov Web site at *http://www.grants.gov.* Similarly, applicants may register for SAM at *https://www.sam.gov* or by calling 1–866–606–8220.

The DUNS number should be identified in the ''Organizational DUNS'' field on Standard Form (SF) 424, ''Application for Federal Assistance.'' Since there are no specific fields for a Commercial and Government Entity (CAGE) code and expiration date, they may be identified anywhere on the Form SF 424. If the applicant does not provide the CAGE code and expiration date and the DUNS number in the application, it will not be considered for funding. The required forms and certifications can be downloaded from the RCDI Web site at: *http://www.rd.usda.gov/programs-services/rural-community-development-initiative-grants.*

*4. Submission Dates and Times*

The deadline for receipt of an application is 4 p.m. local time, August 13, 2015. The application date and time are firm. The Agency will not consider any application received after the deadline. You may submit your application in paper form or electronically through Grants.gov. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX) and postage due applications will not be accepted.

To submit a paper application, the original application package must be submitted to the Rural Development State Office where the applicant's headquarters is located. A listing of Rural Development State Offices can be found via *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf.*

Applications will not be accepted via FAX or electronic mail.

Applicants may file an electronic application at *http://www.grants.gov.* Grants.gov contains full instructions on all required passwords, credentialing, and software. Follow the instructions at Grants.gov for registering and submitting an electronic application. If a system problem or technical difficulty occurs with an electronic application, please use the customer support resources available at the Grants.gov Web site.

Technical difficulties submitting an application through Grants.gov will not be a reason to extend the application deadline. If an application is unable to be submitted through Grants.gov, a paper application must be received in

the appropriate Rural Development State Office by the deadline noted previously.

First time Grants.gov users should carefully read and follow the registration steps listed on the Web site. These steps need to be initiated early in the application process to avoid delays in submitting your application online.

In order to register with System for Award Management (SAM), your organization will need a DUNS number. Be sure to complete the Marketing Partner ID (MPID) and Electronic Business Primary Point of Contact fields during the SAM registration process.

These are mandatory fields that are required when submitting grant applications through Grants.gov. Additional application instructions for submitting an electronic application can be found by selecting this funding opportunity on Grants.gov.

*5. Funding Restrictions*

Meeting expenses. In accordance with 31 U.S.C. 1345, ''Expenses of Meetings,'' appropriations may not be used for travel, transportation, and subsistence expenses for a meeting. RCDI grant funds cannot be used for these meeting-related expenses. Matching funds may, however, be used to pay for these expenses.

RCDI funds may be used to pay for a speaker as part of a program, equipment to facilitate the program, and the actual room that will house the meeting.

RCDI funds cannot be used for meetings; they can, however, be used for travel, transportation, or subsistence expenses for program-related training and technical assistance purposes. Any training not delineated in the application must be approved by the Agency to verify compliance with 31 U.S.C. 1345. Travel and per diem expenses (including meals and incidental expenses) will be allowed in accordance with 2 CFR parts 200 and 400.

**E. Application Review Information**

*1. Evaluation Criteria*

Applications will be evaluated using the following criteria and weights:

(a) Building Capacity and Expertise—Maximum 40 Points

The applicant must demonstrate how they will improve the recipients' capacity, through a program of financial and technical assistance, as it relates to the RCDI purposes.

Capacity-building financial and technical assistance should provide new functions to the recipients or expand existing functions that will enable the recipients to undertake projects in the areas of housing, community facilities, or community and economic development that will benefit the community. Capacity-building financial and technical assistance may include, but is not limited to: Training to conduct community development programs, *e.g.,* homeownership education, or the establishment of minority business entrepreneurs, cooperatives, or micro-enterprises; organizational development, *e.g.,* assistance to develop or improve board operations, management, and financial systems; instruction on how to develop and implement a strategic plan; instruction on how to access alternative funding sources to increase leveraging opportunities; staffing, *e.g.,* hiring a person at intermediary or recipient level to provide technical assistance to recipients.

The program of financial and technical assistance that is to be provided, its delivery, and the measurability of the program's effectiveness will determine the merit of the application.

All applications will be competitively ranked with the applications providing the most improvement in capacity development and measurable activities being ranked the highest.

The narrative response must contain the following items. This list also contains the points for each item.

(1) Describe the nature of financial and technical assistance to be provided to the recipients and the activities that will be conducted to deliver the technical assistance; (10 Points)

(2) Explain how financial and technical assistance will develop or increase the recipient's capacity. Indicate whether a new function is being developed or if existing functions are being expanded or performed more effectively; (7 Points)

(3) Identify which RCDI purpose areas will be addressed with this assistance: Housing, community facilities, or community and economic development; (3 Points)

(4) Describe how the results of the technical assistance will be measured. What benchmarks will be used to measure effectiveness? Benchmarks should be specific and quantifiable; (5 Points)

(5) Demonstrate that it has conducted programs of financial and technical assistance and achieved measurable results in the areas of housing, community facilities, or community and economic development in rural areas. (10 Points)

(6) Provide the name, contact information, and the type and amount of the financial and technical assistance the applicant organization has provided to the following for the last 3 years: (5 Points)

(i) Nonprofit organizations in rural areas.

(ii) Low-income communities in rural areas (also include the type of entity, *e.g.,* city government, town council, or village board).

(iii) Federally recognized tribes or any other culturally diverse organizations.

(b) Soundness of Approach—Maximum 15 Points

The applicant can receive up to 15 points for soundness of approach. The overall proposal will be considered under this criterion. Applicants must list the page numbers in the application that address these factors.

The maximum 15 points for this criterion will be based on the following:

(1) The proposal fits the objectives for which applications were invited, is clearly stated, and the applicant has defined how this proposal will be implemented. (7 Points)

(2) The ability to provide the proposed financial and technical assistance based on prior accomplishments. (6 Points)

(3) Cost effectiveness will be evaluated based on the budget in the application. The proposed grant amount and matching funds should be utilized to maximize capacity building at the recipient level. (2 Points)

(c) Population and Income—Maximum 15 Points

Population is based on the average population from the 2010 census data for the communities in which the recipients are located. The physical address, not mailing address, for each recipient must be used for this criterion. Community is defined for scoring purposes as a city, town, village, county, parish, borough, or census-designated place where the recipient's office is physically located.

The applicant must submit the census data from the following Web site in the form of a printout of the applicable ''Fact Sheet'' to verify the population figures used for each recipient. The data can be accessed on the Internet at *http://www.census.gov;* click on ''American FactFinder,'' fill in field and click ''Go''; the name and population data for each recipient location must be listed in this section.

The average population of the recipient locations will be used and will be scored as follows:

| Population | Scoring (points) |
|---|---|
| 10,000 or less | 5 |
| 10,001 to 20,000 | 4 |
| 20,001 to 30,000 | 3 |
| 30,001 to 40,000 | 2 |
| 40,001 to 50,000 | 1 |

The average of the median household income for the communities where the recipients are physically located will determine the points awarded. The physical address, not mailing address, for each recipient must be used for this criterion. Applicants may compare the average recipient median household income to the State median household income or the national median household income, whichever yields the most points. The national median household income to be used is $51,914.

The applicant must submit the income data in the form of a printout of the applicable information from the following Web site to verify the income for each recipient.

The data being used is from the 2010 census. The data can be accessed on the Internet at *http://www.census.gov;* click on ''American FactFinder,'' fill in field and click ''Go''; the name and income data for each recipient location must be listed in this section. Points will be awarded as follows:

| Average recipient median income | Scoring (points) |
|---|---|
| Less than or equal to 70 percent of state or national median household income | 10 |
| Greater than 70, but less than or equal to 80 percent of state or national median household income | 5 |
| In excess of 80 percent of state or national median household Income | 0 |

(d) State Director's Points Based on Project Merit—Maximum 10 Points

(1) This criterion will be addressed by the Agency, not the applicant.

(2) Up to 10 points may be awarded by the Rural Development State Director to any application(s) that benefits their state regardless of whether the applicant is headquartered in their state. The total points awarded under this criterion, to all applications, will not exceed 10.

(3) When an intermediary submits an application that will benefit a state that is not the same as the state in which the intermediary is headquartered, it is the intermediary's responsibility to notify the State Director of the state which is receiving the benefit of their application. In such cases, State Directors awarding points to applications benefiting their state must notify the reviewing state in writing.

(4) Assignment of any points under this criterion requires a written justification and must be tied to and awarded based on how closely the application aligns with the Rural Development State Office's strategic goals.

(e) Support of Agency's Strategic Goals—Maximum 20 Points

This criterion will be addressed by the Agency, not the applicant. The Agency Administrator may award up to 20 points to any application to the extent that the application supports Strategic Goal One in the USDA Strategic Plan 2014–2018. This plan can be found at the following link: *www.usda.gov/documents/usda-strategic-plan-fy-2014-2018.pdf.*

Points may be awarded to applications that meet at least one of the following six criteria below (note: the maximum points can be given to any one of the following six criteria):

(1) The project is based in a census tract with poverty greater than or equal to 20%;

(2) The project is based in a community (village, town, city, or Census Designated Place) that is 75% CF grant eligible (rural community having a population of 5,000 or less and median household income (MHI) of 60% or less of the state's non-metropolitan median household income (NMHI);

(3) The project's service area includes at least one census tract with poverty greater than or equal to 20%;

(4) The project's service area includes at least one community (village, town, city, or Census Designated Place) that is 75% CF grant eligible (rural community having a population of 5,000 or less and MHI of 60% or less of the state's NMHI);

(5) The project serves a Strikeforce area (see link below).

(6) The project serves a Promise Zone (see link below) and eligible applicant provides evidence of partnership with a Promise Zone Lead Applicant organization.

For a listing of StrikeForce areas and designated Promise Zones, click on the following link: *http://www.usda.gov/wps/portal/usda/usdahome?navid=STRIKE_FORCE,* then click the StrikeForce or Promise Zones button from the left menu. For a mapping tool identifying census tracts with poverty greater than or equal to 20 percent, click on the following link: *http://rdgdwe.sc.egov.usda.gov/rdpoverty/index.html*

*2. Review and Selection Process*

(a) Rating and ranking.

Applications will be rated and ranked on a national basis by a review panel based on the ''Evaluation Criteria'' contained in this Notice.

If there is a tied score after the applications have been rated and ranked, the tie will be resolved by reviewing the scores for ''Building Capacity and Expertise'' and the applicant with the highest score in that category will receive a higher ranking. If the scores for ''Building Capacity and Expertise'' are the same, the scores will be compared for the next criterion, in sequential order, until one highest score can be determined.

(b) Initial screening.

The Agency will screen each application to determine eligibility during the period immediately following the application deadline. Listed below are examples of reasons for rejection from previous funding rounds. The following reasons for rejection are not all inclusive; however, they represent the majority of the applications previously rejected.

(1) Recipients were not located in eligible rural areas based on the definition in this Notice.

(2) Applicants failed to provide evidence of recipient's status, *i.e.,* documentation supporting nonprofit evidence of organization.

(3) Applicants failed to provide evidence of committed matching funds or matching funds were not committed for a period at least equal to the grant performance period.

(4) Application did not follow the RCDI structure with an intermediary and recipients.

(5) Recipients were not identified in the application.

(6) Intermediary did not provide evidence it had been incorporated for at least 3 years as the applicant entity.

(7) Applicants failed to address the ''Evaluation Criteria.''

(8) The purpose of the proposal did not qualify as an eligible RCDI purpose.

(9) Inappropriate use of funds (*e.g.,* construction or renovations).

(10) The applicant proposed providing financial and technical assistance directly to individuals.

(11) The application package was not received by closing date and time.

**F. Federal Award Administration Information**

*1. Federal Award Notice*

Within the limit of funds available for such purpose, the awarding official of the Agency shall make grants in ranked order to eligible applicants under the procedures set forth in this Notice.

Successful applicants will receive a selection letter by mail containing

instructions on requirements necessary to proceed with execution and performance of the award. This letter is not an authorization to begin performance. In addition, selected applicants will be requested to verify that components of the application have not changed at the time of selection and on the award obligation date, if requested by the Agency.

The award is not approved until all information has been verified, and the awarding official of the Agency has signed Form RD 1940–1, ''Request for Obligation of Funds'' and the grant agreement.

Unsuccessful applicants will receive notification including appeal rights by mail.

*2. Administrative and National Policy Requirements*

Grantees will be required to do the following:

(a) Execute a Rural Community Development Initiative Grant Agreement.

(b) Execute Form RD 1940–1, ''Request for Obligation of Funds.''

(c) Use Form SF 270, ''Request for Advance or Reimbursement,'' to request reimbursements. Provide receipts for expenditures, timesheets and any other documentation to support the request for reimbursement.

(d) Provide financial status and project performance reports on a quarterly basis starting with the first full quarter after the grant award.

(e) Maintain a financial management system that is acceptable to the Agency.

(f) Ensure that records are maintained to document all activities and expenditures utilizing RCDI grant funds and matching funds. Receipts for expenditures will be included in this documentation.

(g) Provide annual audits or management reports on Form RD 442–2, ''Statement of Budget, Income and Equity,'' and Form RD 442–3, ''Balance Sheet,'' depending on the amount of Federal funds expended and the outstanding balance.

(h) Collect and maintain data provided by recipients on race, sex, and national origin and ensure recipients collect and maintain the same data on beneficiaries. Race and ethnicity data will be collected in accordance with OMB **Federal Register** notice, ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' (62 FR 58782), October 30, 1997. Sex data will be collected in accordance with Title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be available upon request by the Agency.

(i) Provide a final project performance report.

(j) Identify and report any association or relationship with Rural Development employees.

(k) The intermediary and recipient must comply with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, Executive Order 12250, and 7 CFR part 1901, subpart E.

(l) The grantee must comply with policies, guidance, and requirements as described in the following applicable Code of Federal Regulations, and any successor regulations:

(i) 2 CFR parts 200 and 400 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements For Federal Awards).

(ii) 2 CFR parts 417 and 180 (Government-wide Debarment and Suspension (Nonprocurement)

(m) Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants,'' Must be signed by corporate applicants who receive an award under this Notice.

*3. Reporting*

After grant approval and through grant completion, you will be required to provide the following, as indicated in the Grant Agreement:

(a) SF–425, ''Federal Financial Report'' and SF–PPR, ''Performance Progress Report'' will be required on a quarterly basis (due 30 working days after each calendar quarter). The Performance Progress Report shall include the elements described in the grant agreement.

(b) Final financial and performance reports will be due 90 calendar days after the period of performance end date.

(c) A summary at the end of the final report with elements as described in the grant agreement to assist in documenting the annual performance goals of the RCDI program for Congress.

**G. Federal Awarding Agency Contact**

Contact the Rural Development office in the State where the applicant's headquarters is located. A list of Rural Development State Offices can be found via *http://www.rd.usda.gov/files/RCDI_State_Contacts.pdf*.

**H. Other Information**

Survey on Ensuring Equal Opportunity for Applicants, OMB No. 1894–0010 (applies only to nonprofit applicants only—submission is optional).

No reimbursement will be made for any funds expended prior to execution of the RCDI Grant Agreement unless the intermediary is a non-profit or educational entity and has requested and received written Agency approval of the costs prior to the actual expenditure.

This exception is applicable for up to 90 days prior to grant closing and only applies to grantees that have received written approval but have not executed the RCDI Grant Agreement.

The Agency cannot retroactively approve reimbursement for expenditures prior to execution of the RCDI Grant Agreement.

*Program Definitions*

Agency—The Rural Housing Service (RHS) or its successor.

Beneficiary—Entities or individuals that receive benefits from assistance provided by the recipient.

Capacity—The ability of a recipient to implement housing, community facilities, or community and economic development projects.

Conflict of interest—A situation in which a person or entity has competing personal, professional, or financial interests that make it difficult for the person or business to act impartially. Regarding use of both grant and matching funds, Federal procurement standards prohibit transactions that involve a real or apparent conflict of interest for owners, employees, officers, agents, or their immediate family members having a financial or other interest in the outcome of the project; or that restrict open and free competition for unrestrained trade. Specifically, project funds may not be used for services or goods going to, or coming from, a person or entity with a real or apparent conflict of interest, including, but not limited to, owner(s) and their immediate family members. An example of conflict of interest occurs when the grantee's employees, board of directors, or the immediate family of either, have the appearance of a professional or personal financial interest in the recipients receiving the benefits or services of the grant.

Federally recognized tribes—Tribal entities recognized and eligible for funding and services from the Bureau of Indian Affairs, based on the most recent notice in the **Federal Register** published by the Bureau of Indian Affairs. Tribally Designated Housing Entities are eligible RCDI recipients.

Financial assistance—Funds, not to exceed $10,000 per award, used by the intermediary to purchase supplies and equipment to build the recipient's capacity.

Funds—The RCDI grant and matching money.

Intermediary—A qualified private, nonprofit (including faith-based and community organizations and philanthropic organizations), or public (including tribal) organization that provides financial and technical assistance to multiple recipients.

Low-income rural community—An authority, district, economic development authority, regional council, or unit of government representing an incorporated city, town, village, county, township, parish, or borough whose income is at or below 80 percent of either the state or national Median Household Income as measured by the 2010 Census.

Matching funds—Cash or confirmed funding commitments. Matching funds must be at least equal to the grant amount and committed for a period of not less than the grant performance period.

Recipient—The entity that receives the financial and technical assistance from the Intermediary. The recipient must be a nonprofit community-based housing and development organization, a low-income rural community or a federally recognized Tribe.

Rural and rural area—Any area other than (i) a city or town that has a population of greater than 50,000 inhabitants; and (ii) the urbanized area contiguous and adjacent to such city or town.

Technical assistance—Skilled help in improving the recipient's abilities in the areas of housing, community facilities, or community and economic development.

*Non-Discrimination Policy*

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

*To File a Program Complaint*

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form.

You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov*.

*Persons With Disabilities*

Individuals who are deaf, hard of hearing, or have speech disabilities and you wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities who wish to file a program complaint, please see information above on how to contact us by mail directly or by email.

If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

*Appeal Process*

All adverse determinations regarding applicant eligibility and the awarding of points as part of the selection process are appealable pursuant to 7 CFR part 11. Instructions on the appeal process will be provided at the time an applicant is notified of the adverse decision.

In the event the applicant is awarded a grant that is less than the amount requested, the applicant will be required to modify its application to conform to the reduced amount before execution of the grant agreement. The Agency reserves the right to reduce or withdraw the award if acceptable modifications are not submitted by the awardee within 15 working days from the date the request for modification is made. Any modifications must be within the scope of the original application.

Dated: May 11, 2015.

**Tony Hernandez,**

*Administrator, Rural Housing Service.*

[FR Doc. 2015–11741 Filed 5–14–15; 8:45 am]

BILLING CODE 3410–XV–P

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Michigan Advisory Committee for a Meeting To Discuss Potential Project Topics

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Michigan Advisory Committee (Committee) will hold a meeting on Monday, July 20, 2015, at 3:00 p.m. EST for the purpose of discussing civil rights topics in the state and begin consideration of future projects. The Committee met on May 11 to begin the discussion on civil rights issues in Michigan and will continue the discussion during this meeting, including review of concept papers developed by Committee members.

Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 888–455–2263, conference ID: 2627011. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement at the end of the meeting. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office by August 20, 2015. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to Administrative Assistant, Carolyn Allen at *callen@usccr.gov.* Persons who desire additional

information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=255* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

**Agenda**

Welcome and Introductions
Donna Budnick, Chair
Discussion of civil rights issues in Michigan
Michigan Advisory Committee Members
Future plans and actions
Adjournment

**DATES:** The meeting will be held on Monday, July 20, 2015, at 3:00 p.m. EST.

*Public Call Information:*

Dial: 888–455–2263
Conference ID: 2627011

**FOR FURTHER INFORMATION CONTACT:** David Mussatt at *dmussatt@usccr.gov* or 312–353–8311.

Dated: May 12, 2015.

**David Mussatt,**

*Chief, Regional Programs Unit.*

[FR Doc. 2015–11794 Filed 5–14–15; 8:45 am]

**BILLING CODE 6335–01–P**

## DEPARTMENT OF COMMERCE

### Economic Development Administration

### Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

**AGENCY:** Economic Development Administration, Department of Commerce.

**ACTION:** Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[4/24/2015 through 5/11/2015]

| Firm name | Firm address | Date accepted for investigation | Product(s) |
|---|---|---|---|
| Goodness Greeness, Inc. | 5959 South Lowe Avenue, Chicago, IL 60621. | 5/6/2015 | ''The firm orders, procures, transports, inspects, packages, sells and delivers organic fruit, vegetables and herbs such as Navel Oranges, Grapefruit, Lemons, Cabbage, Gold Potatoes, Yams, Russet Potatoes, Peppers, Celery and Rainbow Carrots.'' |
| Effort Foundry, Inc .... | 6980 Chrisphalt Drive, Bath, PA 18014. | 5/5/2015 | The firm manufactures iron, seals castings and bearing housings. |

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: May 11, 2015.

**Michael S. DeVillo,**

*Eligibility Examiner.*

[FR Doc. 2015–11738 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–WH–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[Order No. 1983]**

### Approval of Subzone Status; Spectro Coating Corporation d/b/a Claremont Flock, LLC, Leominster, Massachusetts

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

*Whereas,* the Foreign-Trade Zones Act provides for ''. . .the establishment. . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

*Whereas,* the Board's regulations (15 CFR part 400) provide for the establishment of subzones for specific uses;

*Whereas,* the Massachusetts Port Authority, grantee of Foreign-Trade Zone 27, has made application to the Board for the establishment of a subzone at the facility of Spectro Coating Corporation d/b/a Claremont Flock, LLC, located in Leominster, Massachusetts (FTZ Docket B–6–2015, docketed 02–03–2015);

*Whereas,* notice inviting public comment has been given in the **Federal**

**Register** (80 FR 7413, 02–10–2015) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

*Whereas,* the Board adopts the findings and recommendations of the examiner's memorandum, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

*Now, therefore,* the Board hereby approves subzone status at the facility of Spectro Coating Corporation d/b/a Claremont Flock, LLC, located in Leominster, Massachusetts (Subzone 27N), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.13.

Signed at Washington, DC, this 8th day of May 2015.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.*

Attest:_____

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015–11855 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## Foreign-Trade Zones Board

**[B–03–2015]**

### Foreign-Trade Zone (FTZ) 84—Houston, Texas; Authorization of Production Activity MHI Compressor International Corporation (Gas Compressors, Compressor Sets, Electrical Generators and Generating Sets), Pearland, Texas

On January 12, 2015, MHI Compressor International Corporation submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 84—Site 37, in Pearland, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (80 FR 4868, January 29, 2015). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: May 12, 2015.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015–11843 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## Foreign-Trade Zones Board

**[Order No. 1982]**

### Reorganization and Expansion of Foreign-Trade Zone 49 Under Alternative Site Framework, Newark/Elizabeth, New Jersey

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

*Whereas,* the Board adopted the alternative site framework (ASF) (15 CFR 400.2(c)) as an option for the establishment or reorganization of zones;

*Whereas,* the Port Authority of New York and New Jersey, grantee of Foreign-Trade Zone 49, submitted an application to the Board (FTZ Docket B–56–2014, docketed 08–11–2014; amended 01–21–2015) for authority to reorganize and expand FTZ 49 under the ASF with a service area that includes the County of Hudson in its entirety, as well as those parts of the Counties of Bergen, Essex, Passaic, Union, Middlesex, Monmouth, Morris and Somerset, New Jersey, which lie within the Port Authority's jurisdiction known as the Port District, within and adjacent to the Newark/Elizabeth Customs and Border Protection port of entry. FTZ 49's existing Sites 1, 2, 3, 4, 6 and 13 would be categorized as magnet sites, and Sites 5, 14 and 15 would be categorized as usage-driven sites;

*Whereas,* notice inviting public comment was given in the **Federal Register** (79 FR 48726, August 18, 2014) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and

*Whereas,* the Board adopts the findings and recommendation of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

*Now, therefore,* the Board hereby orders:

The amended application to reorganize and expand FTZ 49 under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, to an ASF sunset provision for magnet sites that would terminate authority for Sites 2, 3, 4, 6 and 13 if not activated within five years from the month of approval, and to an ASF sunset provision for usage-driven sites that would terminate authority for Sites 5, 14 and 15 if no foreign-status merchandise is admitted for a *bona fide* customs purpose within three years from the month of approval.

Signed at Washington, DC, this 8 day of May 2015.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.*

ATTEST:_____

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015–11856 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

### Mid-Atlantic Fishery Management Council (MAFMC); Fisheries of the Northeastern United States; Public Meetings

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

**ACTION:** Notice of public scoping meetings.

**SUMMARY:** The Mid-Atlantic Fishery Management Council will hold five scoping hearings in June 2015 related to blueline tilefish management. The Council is considering developing a fishery management plan (FMP) for blueline tilefish and/or other deepwater species, or adding blueline tilefish to the existing golden tilefish FMP. There will also be a separate written comment period for Amendment scoping, which will be described in an upcoming **Federal Register** announcement as a ''Notice of Intent (NOI)'' to potentially develop an EIS that accompanies the Amendment. That NOI will also contain information regarding these scoping hearings, but to provide the public with sufficient advance notice of the hearings, this notice is being published now since the NOI will likely publish shortly before these hearings.

**DATES:** The meetings will be held over several weeks between June 1, 2015 and June 18, 2015 as described in **SUPPLEMENTARY INFORMATION** below.

**ADDRESSES:** See **SUPPLEMENTARY INFORMATION** for locations.

*Council address:* Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

*Comments:* Comments will be taken at all scoping hearings. A separate **Federal Register** announcement will be

published soon that provides additional information on how to make written comments.

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* (see ''Upcoming Events'') also has details on the meeting locations and background materials. A scoping informational document and presentation recording will be posted to *http://www.mafmc.org/actions/blueline-tilefish* no later than May 26, 2015.

**SUPPLEMENTARY INFORMATION:** There will be five scoping meetings with the following dates/times/locations:

1. Monday, June 1, 2015, 6 p.m., Hyatt Place Long Island/East End, 451 E. Main St., Riverhead, NY 11901; telephone: (631) 208–0002.
2. Tuesday, June 2, 2015, 6 p.m., Congress Hall Hotel, 251 Beach Ave., Cape May, NJ 08204; telephone: (888) 944–1816.
3. Tuesday, June 16, 2015, 6 p.m., Dare County Administration Building, Commissioners Meeting Room, 954 Marshall C. Collins Drive, Manteo, NC 27954; telephone: (252) 475–5700.
4. Wednesday, June 17, 2015, 6 p.m., Hilton Virginia Beach Oceanfront, 3001 Atlantic Ave., Virginia Beach, VA 23451; telephone: (757) 213–3000.
5. Thursday, June 18, 2015, 5 p.m., Ocean City Chamber of Commerce, Eunice Q. Sorin Visitor & Conference Center, 12320 Ocean Gateway, Ocean City, MD 21842; telephone: (410) 213–0552.

The South Atlantic Fishery Management Council (SAFMC) manages blueline tilefish south of Virginia, but there is currently (as of May 11, 2015) no management of blueline tilefish in Federal waters north of North Carolina. Virginia and Maryland have instituted regulations for state waters, but catches in any Federal waters north of North Carolina may be landed from Delaware north without restriction. Blueline tilefish are susceptible to overfishing due to their biology (relatively long-lived, sedentary, slow growing, and late maturing) so the Council is considering developing management measures. These potential measures could be considered via an amendment to the Council's golden tilefish FMP, or a new FMP for blueline tilefish and/or other deep-water fish such as sand tilefish, snowy grouper, and black-bellied rosefish. Management measures could include a definition of the management unit, as well as acceptable biological catches, annual catch limits, trip limits, essential fish habitat, etc.

For waters north of North Carolina, in response to recent catch increases the Council has already requested that NMFS take emergency action to implement a 300 pound (whole weight) commercial trip limit and a seven fish per-person recreational possession limit. This request was the result of a February 25, 2015 Council Meeting, the details of which may be found at: *http://www.mafmc.org/briefing/2015/february-2014-blueline-tilefish-webinar-meeting.* These emergency measures are intended to prevent depletion of blueline tilefish off the Mid-Atlantic on an interim basis (for a maximum of 360 days) while the Council develops long-term management measures through the normal rulemaking process. NMFS has not decided whether and/or how to respond to the Council's request.

Through the SAFMC's Amendment 32 (*http://sero.nmfs.noaa.gov/sustainable_fisheries/s_atl/sg/2014/am32/*), NMFS implemented a 112 pound (whole weight) commercial trip limit and a one fish per boat per trip recreational trip limit (with a limited season) for the South Atlantic management unit that extends to waters off the North Carolina/Virginia border. The SAFMC has also requested that the Amendment 32 limits be extended north for all Federal waters off the U.S. East Coast via an emergency rule. The outcome of the Mid-Atlantic Fishery Management Council's and SAFMC's emergency requests was not known at the time this notice was submitted. However, because any emergency rule can only be in effect for a maximum of 360 days, the Council is moving ahead with scoping for an amendment to develop long-term management and conservation measures for blueline tilefish off the Mid-Atlantic through the normal rule-making process.

This is the first and best opportunity for members of the public to raise concerns related to the scope of issues that will be considered in the Amendment. The Council needs your input both to identify management issues and develop effective alternatives. Your comments early in the amendment development process will help us address issues of public concern in a thorough and appropriate manner. Comment topics could include the scope of issues in the amendment, concerns and potential alternatives related to blueline tilefish management, and the appropriate level of environmental analysis. Comments can be made during the scoping hearings as detailed above or in writing once the official NOI publishes. After scoping, the Council plans to develop a range of management alternatives to be considered and prepare a draft Environmental Impact Statement (DEIS) and/or other appropriate environmental analyses. These analyses will consider the impacts of the management alternatives being considered. Following a review of any comments on the draft analyses, the Council will then choose preferred management measures for submission with a Final EIS or Environmental Assessment to the Secretary of Commerce for publishing of a proposed and then final rule, both of which have additional comment periods.

### Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: May 12, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–11759 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–22–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD895**

### FY 15 Coastal Ecosystem Resiliency Grants Program

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

**ACTION:** Notice of funding availability.

**SUMMARY:** The principal objective of the National Marine Fisheries Service's (NMFS) Coastal Ecosystem Resiliency Grants Program is to implement projects that use a proactive approach to improve or restore coastal habitat to: (1) Strengthen the resilience of our marine or coastal ecosystems to decrease the vulnerability of communities to extreme weather; and (2) support sustainable fisheries and contribute to the recovery of protected resources. See the full Coastal Ecosystem Resiliency Grants Federal Funding Opportunity (FFO), located on Grants.gov as described in the **ADDRESSES** section, for a complete description of program goals and how applications will be evaluated. Note that this funding opportunity is one of two competitions being administered by NOAA to build coastal resilience. The companion competition, the Regional

Coastal Resilience Grants Program, is being administered by NOAA's National Ocean Service to support implementation of actions that directly build resilience of U.S. coastal communities using regional approaches. The Regional Coastal Resilience Grants FFO is expected to be posted in May 2015, and may be found on *www.Grants.gov.*

**DATES:** Applications must be postmarked, provided to a delivery service, or received by *www.Grants.gov* by 11:59 p.m. Eastern Time on July 2, 2015. Use of a delivery service must be documented with a receipt. No facsimile or electronic mail applications will be accepted. In addition, applicants are advised that they must provide approval from the State Governor as evidenced by a letter or other form of documented correspondence for the proposed project by July 31, 2015. Before awards are made, NOAA will verify that correspondence from the State Governor has been received. See also Section III.C of the Coastal Ecosystem Resiliency Grants FFO.

**ADDRESSES:** Complete application packages, including required Federal forms and instructions, can be found on *www.Grants.gov* by searching for Funding Opportunity Number NOAA–NMFS–HCPO–2015–2004410. If a prospective applicant is having difficulty downloading the application forms from *www.Grants.gov,* contact *www.Grants.gov* Customer Support at 1–800–518–4726 or *support@Grants.gov.*

**FOR FURTHER INFORMATION CONTACT:** For further information, contact Melanie Gange at (301) 427–8664, or by email at *Melanie.Gange@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

*Statutory Authority:* Fish and Wildlife Coordination Act 16 U.S.C. 661, as amended by the Reorganization Plan No. 4 of 1970; Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006, 16 U.S.C. 1891a; and Endangered Species Act, 16 U.S.C. 1535.

*Catalog of Federal Domestic Assistance (CFDA):* 11.463.

## Program Description

As noted above, the principal objective of the Coastal Ecosystem Resiliency Grants Program is to implement projects that use a proactive approach to improve or restore coastal habitat to: (1) Strengthen the resilience of our marine and coastal ecosystems to decrease the vulnerability of communities to extreme weather; and (2) support sustainable fisheries and contribute to the recovery of protected resources. Applications should demonstrate how the proposed project will enhance the resiliency of marine and coastal ecosystems to the impacts of extreme weather and changing environmental conditions thereby increasing community resilience and providing habitat to threatened and endangered species listed under the Endangered Species Act (hereafter, Listed Species), fish stocks managed under the Magnuson-Stevens Fishery Conservation and Management Act (hereafter, Managed Species), or other marine and coastal species with a nexus to NMFS management (such as through the Atlantic Coastal Fisheries Cooperative Management Act, Atlantic Striped Bass Conservation Act, Marine Mammal Protection Act, Coral Reef Conservation Act, or NMFS Species of Concern). Successful applications will (1) identify an issue limiting the resiliency of marine or coastal ecosystems to extreme weather events or changing environmental conditions at the proposed project site; (2) identify the proposed project's outcome goal(s) and describe in detail the actions and on-the-ground restoration to be undertaken to enhance resiliency and reduce risk and; (3) describe the measurable impact on the ecosystem, target species, and surrounding coastal communities to benefit from the proposed habitat restoration project. Applications selected for funding through this solicitation will primarily be funded through cooperative agreements.

Section IV.B. of the FFO describes the suggested information to include in the application narrative. Supplemental Guidance regarding application writing, a checklist to submit a complete application, and FAQs about this solicitation and the Regional Coastal Resilience Grants Program being administered by NOAA's National Ocean Service can be found at *www.restoration.noaa.gov/partnerresources* and *www.habitat.noaa.gov/funding/coastalresiliency.html,* respectively. Prospective applicants are strongly encouraged to contact NOAA Restoration Center staff before submitting an application to discuss their NOAA Coastal Ecosystem Resiliency project ideas with respect to technical merit and NOAA's objectives. NOAA will make every effort to respond to prospective applicants on a first come, first served basis. These discussions will not include review of draft proposals or site visits during the application period.

This funding opportunity is one of two FFOs being administered by NOAA to build coastal resilience. The companion competition, Regional Coastal Resilience Grants Program, is being administered by NOAA's National Ocean Service to undertake activities that build resilience of coastal regions, communities, and economic sectors to the negative impacts from extreme weather events, climate hazards, and changing ocean conditions. The Regional Coastal Resilience Grants FFO is expected to be posted in May of 2015 and may be found on *www.grants.gov.*

## Funding Availability

Total anticipated funding for all awards is up to $4 million, subject to the availability of appropriations. NOAA anticipates typical awards will range from $500,000 to $1 million. NOAA will not accept applications requesting less than $200,000 or more than $2 million in Federal funds from NOAA under this solicitation and the exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA. Any funds provided to successful applicants will be at the discretion of the NOAA Office of Habitat Conservation and the NOAA Grants Management Division (GMD). In no event will NOAA or the Department of Commerce be responsible for application preparation costs if programs fail to receive funding or are cancelled because of other agency priorities. Publication of this notice does not oblige NOAA to award any specific project or to obligate any available funds and there is no guarantee that sufficient funds will be available to make awards for all top-ranked applications. The number of awards to be made as a result of this solicitation will depend on the number of eligible applications received, the amount of funds requested for coastal ecosystem resiliency projects, and the merit and ranking of the applications.

## Eligibility

Eligible applicants are institutions of higher education, non-profits, commercial (for profit) organizations, U.S. territories, and state, local and Native American tribal governments. Applications from individuals, Federal agencies, or employees of federal agencies will not be considered. Individuals and Federal agencies are strongly encouraged to work with states, non-governmental organizations, municipal and county governments, and others that are eligible to apply. In addition, NOAA will only award funds to projects that receive and demonstrate approval of the State's Governor to implement the proposed project as evidenced by a letter or other form of

documented correspondence by July 31, 2015. Funds awarded under this program must be matched with non-federal funds (cash or in-kind services) at a 2:1 ratio of Federal-to-non-federal contributions. Applications selected for funding will be bound by the percentage of cost sharing reflected in the award document signed by the NOAA Grants Officer.

**Evaluation and Selection Procedures**

The general evaluation criteria and selection factors that apply to full applications to this funding opportunity are summarized below. Further information about the evaluation criteria and selection factors can be found in the full FFO announcement in *www.Grants.gov* (Funding Opportunity Number NOAA–NMFS–HCPO–2015–2004410).

**Evaluation Criteria**

Reviewers will assign scores to applications ranging from 0 to 100 points based on the following five standard NOAA evaluation criteria and respective weights specified below. Applications that best address these criteria will be most competitive.

1. Importance and Applicability (35 points): This criterion ascertains whether there is intrinsic value in the proposed work and/or relevance to NOAA, federal, regional, state or local activities.
2. Technical/Scientific Merit (25 points): This criterion assesses whether the project activity or approach is technically sound, if the methods are appropriate, and whether there are clear goals and objectives.
3. Overall Qualifications of Applicant (10 points): This criterion ascertains whether the applicant possesses the necessary education, experience, training, facilities, and administrative resources to support the proposed award.
4. Project Costs (20 points): This criterion evaluates the budget to determine if it is realistic and commensurate with the project's needs and time-frame.
5. Outreach and Education (10 points): NOAA assesses whether the award can deliver a focused and effective education and outreach strategy regarding NOAA's mission to protect the Nation's natural resources.

**Review and Selection Process**

Applications will undergo an initial administrative review to determine if they are eligible and complete, per Section III of the full FFO posted at *www.Grants.gov.* Eligible applications will undergo a technical review, ranking, and selection process by three or more merit reviewers to determine how well they meet the program priorities and evaluation criteria of this solicitation and the mission and goals of NOAA. After the technical review, a panel may meet to make final recommendations to the Selecting Official (SO) regarding which applications best meet the program objectives and priorities (see Sections I.A. and I.B. of the full FFO). The SO anticipates recommending applications for funding in rank order unless an application is justified to be selected out of rank order based upon one or more of the following selection factors: (1) Availability of funding; (2) Balance/distribution of funds: (a) By geographic area, (b) by type of institutions, (c) by type of partners, (d) by research areas; or (e) by project types; (3) Whether the project duplicates other projects funded or considered for funding by NOAA or other federal agencies; (4) Program priorities and policy factors set out in section I.A. and I.B. of the FFO; (5) An applicant's prior award performance; (6) Partnerships and/or participation of targeted groups; and (7) Adequacy of information necessary for NOAA staff to make a NEPA determination and draft necessary documentation before recommendations for funding are made to the NOAA GMD. Hence, awards may not necessarily be made to the highest-scored applications. In addition, as noted above, applicants must provide NOAA with documentation of approval from the State Governor for the proposed project by July 31, 2015 in order to receive an award. Unsuccessful applicants will be notified that their application was not among those recommended for funding. Unsuccessful applications submitted in hard copy will be kept on file in accordance with NOAA records requirements and then destroyed.

**Intergovernmental Review**

Applications submitted under the FFO are subject to the provisions of Executive Order 12372, ''Intergovernmental Review of Programs.'' Any applicant submitting an application for funding is required to complete item 16 on Form SF–424 regarding clearance by the State Single Point of Contact (SPOC). To find out about and comply with a State's process under Executive Order 12372, the names, addresses and phone numbers of participating SPOC's are listed on the Office of Management and Budget's home page at: *http://www.whitehouse.gov/omb/grants_spoc.*

**Limitation of Liability**

In no event will NOAA or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige NOAA to award any specific project or to obligate any available funds.

**National Environmental Policy Act**

NOAA must analyze the potential environmental impacts, as required by the National Environmental Policy Act (NEPA), for applicant projects or proposals which are seeking NOAA federal funding opportunities. Consequently, as part of an applicant's package, and under their description of their program activities, applicants are required to provide detailed information on the activities to be conducted, locations, sites, species and habitat to be affected, possible construction activities, and any environmental concerns that may exist. Applicants may also be requested to assist NOAA in drafting of an environmental assessment, or in identifying and implementing feasible measures to reduce or avoid any identified adverse environmental impacts of their proposal. The failure to do so shall be grounds for not selecting an application. Further details regarding NOAA's compliance with NEPA can be found in the full Federal Funding Opportunity.

**The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements**

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of December 30, 2014 (79 FR 78390) are applicable to this solicitation.

**Paperwork Reduction Act**

This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, and SF–LLL and CD–346 has been approved by the Office of Management and Budget (OMB) under the respective control numbers 0348–0043, 0348–0044, 0348–0040, 0348–0046, and 0605–0001. Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

**Executive Order 12866**

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

**Executive Order 13132 (Federalism)**

It has been determined that this notice does not contain policies with implications as that term is defined in Executive Order 13132.

**Administrative Procedure Act/ Regulatory Flexibility Act**

Prior notices and an opportunity for public comment are not required by the Administrative Procedure Act or any other law for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements for the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

**Frederick C. Sutter,**

*Director, Office of Habitat Conservation, National Marine Fisheries Service.*

[FR Doc. 2015–11769 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**RIN 0648–XD870**

## Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Shallow Geohazard Survey in the Beaufort Sea, Alaska

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

**ACTION:** Notice; proposed incidental harassment authorization; request for comments.

**SUMMARY:** NMFS received an application from Hilcorp Alaska, LLC. (Hilcorp) for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to shallow geohazard survey in the Beaufort Sea, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to Hilcorp to take, by Level B harassment only, 6 species of marine mammals during the specified activity.

**DATES:** Comments and information must be received no later than June 15, 2015.

**ADDRESSES:** Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.Guan@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

A copy of the application, which contains several attachments, including Hilcorp's marine mammal mitigation and monitoring plan (4MP), used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

**FOR FURTHER INFORMATION CONTACT:** Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:**

### Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

### Summary of Request

On December 1, 2014, NMFS received an application from Hilcorp for the taking of marine mammals incidental to shallow geohazard surveys in the Beaufort Sea. After receiving NMFS comments, Hilcorp submitted a revised IHA application on January 5, 2015. In addition, Hilcorp submitted a 4MP on January 21, 2015. NMFS determined that the application was adequate and complete on February 9, 2015.

The proposed activity would occur between July 1 and September 30, 2015. The actual survey is expected to be complete in 45 days, including weather and equipment downtime. Underwater noises generated from the sonar used for the survey are likely to result Level B harassment of individuals of 6 species of marine mammals.

### Description of the Specified Activity

*Overview*

Hilcorp plans to conduct a shallow geohazard survey and Strudel Scour survey with a transition zone component on state lands, and in federal and state waters of Foggy Island Bay in the Beaufort Sea during the open water season of 2015. The scope of this request is limited to the activities that will be conducted during the 2015 open water evaluation of the proposed Liberty field development.

*Dates and Duration*

Hilcorp seeks incidental harassment authorization for the period July 1 to September 30, 2015. The survey is expected to take approximately 45 days

to complete, including weather and equipment downtime. About 25% of downtime is included in this total, so the actual number of days that equipment are expected to be operating is estimated at 34, based on a continuous 24-hr. operation.

*Specified Geographic Region*

The project area of the proposed Liberty shallow geohazard survey lies within Foggy Island Bay as shown in Figure 1 of Hilcorp's IHA application. The project area is 2.5 $mi^2$ in water depths ranging from 3 to 20 ft.

*Detailed Description of Activities*

(1) Survey Designs

The proposed sonar survey vessel (M/V *Sidewinder* or equivalent) is about 40 × 14 feet in size. The sub-bottom profilers and magnetometer will be deployed from the vessel. The echosounder and side scan sonar will be hull-mounted. No equipment will be placed on the sea floor as part of survey activities. Because of the extremely shallow project area, additional small vessel(s) may be utilized to safely extend vessel operations for data collection.

The total planned survey lines are approximately 300 miles, not including turns and cross-lines. Data will be acquired along the subsea pipeline corridor area using the single-beam or multibeam echosounder, side scan sonar, sub-bottom profilers, and the magnetometer. Because of the shallow nature of the project area and small size of the vessel, systems will be towed in optimal groupings that best facilitate safe operations and data quality. As necessary, a small vessel may be used to extend data collection into shallow waters. Planned survey lines will be designed to acquire 150% side scan sonar data coverage or as mandated, with line spacing dependent upon water depth. A 300 m corridor around the centerline of the proposed pipeline area will be covered.

(2) Acoustic Sources

*Multibeam Echo Sounder and Side Scan Sonar*

A single-beam or multibeam echosounder and side scan sonar will be used to obtain high accuracy information regarding bathymetry of the seafloor. For accurate object detection, a side scan sonar survey is required to complement a multibeam echosounder survey.

The proposed multibeam echosounder operates at an rms source level of a maximum of 220 dB re 1 μPa @1 m. The multibeam echosounder emits high frequency (240 kHz) energy in a fan-shaped pattern of equidistant or equiangular beam spacing (Table 1). The beam width of the emitted sound energy in the along-track direction is 1.5 degrees, while the across track beam width is 1.8 degrees. The maximum ping rate of the multibeam echosounder is 40 Hz.

The proposed single-beam echosounder operates at an rms source level of approximately 220 dB re 1 μPa @1 m (Table 1). The transducer selected uses a frequency of 210 kHz and has a ping rate of up to 20 Hz. The transducer's beam width is approximately 3 degrees.

The proposed side scan sonar system will operate at about 400 kHz and 900 kHz. The rms source level is 215 dB re 1μPa @1 m. The sound energy is emitted in a narrow fan-shaped pattern, with a horizontal beam width of 0.45 degrees for 400 kHz and 0.25 degrees at 900 kHz, with a vertical beam width of 50 degrees (Table 1). The maximum ping rate is 75 Hz.

*Sub-Bottom Profiler*

The proposed high-resolution sub-bottom profiler operates at an rms source level of 210db re 1 μPa @1 m. The proposed system emits energy in the frequency bands of 2 to 24 kHz. The beam width is 15 to 24 degrees (Table 1). Typical pulse rate is between 3 and 10 Hz.

The proposed low-resolution sub-bottom profiler operates at an rms source level of 212db re 1 μPa @1 m. This secondary sub-bottom profiler will be utilized as necessary to increase sub-bottom profile penetration. The proposed system emits energy in the frequency bands of 1 to 4 kHz.

TABLE 1—SOURCE CHARACTERISTICS OF THE PROPOSED GEOPHYSICAL SURVEY EQUIPMENT TO BE USED DURING THE LIBERTY GEOHAZARD SURVEY

| Equipment | Sample equipment model type | Operating frequency | Along track beam width | Across track beam width | Source level (dB re 1 μPa @1 m, rms) |
|---|---|---|---|---|---|
| Multibeam echosounder | Reson 7101 SV | 240 kHz | 1.5° | 1.8° | 220 |
| Single-beam echosounder | Odom | 210 kHz | 3° | 3° | 220 |
| Side scan sonar | Edgetech 4125 | 400 kHz/900 kHz | 0.5° | 50° | 215 |
| High resolution (CHIRP) sub-bottom profiler. | Edgetech 3200 | 2 to 24 kHz | 15° to 24° | 15° to 24° | 210 |
| Low resolution sub-bottom profiler | Applied Acoustics AA251 | 1 to 4 kHz | n/a | n/a | 212 |
| Alternative multibeam echosounder | Norbit IWBMS | 400 kHz | 1.9° | 0.9° | 218 |

**Description of Marine Mammals in the Area of the Specified Activity**

The Beaufort Sea supports a diverse assemblage of marine mammals. Table 2 lists the 12 marine mammal species under NMFS jurisdiction with confirmed or possible occurrence in the proposed project area.

**Table 2. Marine mammal species with confirmed or possible occurrence in the proposed shallow geohazard survey area.**

| Common Name | Scientific Name | Occurrence | Seasonality | Range | Abundance |
|---|---|---|---|---|---|
| **Odontocetes** | | | | | |
| Beluga whale (Beaufort Sea stock) | *Delphinapterus leucas* | Common | Mostly spring and fall with some in summer | Mostly Beaufort Sea | 39,258 |
| Beluga whale (eastern Chukchi Sea stock) | | Common | Mostly spring and fall with some in summer | Mostly Chukchi Sea | 3,710 |
| Killer whale | *Orcinus orca* | Extralimital | Mostly summer and early fall | California to Alaska | 552 |
| Harbor porpoise | *Phocoena phocoena* | Extralimital | Mostly summer and early fall | California to Alaska | 48,215 |
| Narwhal | *Monodon monoceros* | Extralimital | Year round | Arctic Ocean | 45,358 |
| **Mysticetes** | | | | | |
| Bowhead whale* | *Balaena mysticetus* | Common | Mostly spring and fall with some in summer | Russia to Canada | 19,534 |
| Gray whale | *Eschrichtius robustus* | Somewhat common | Mostly summer | Mexico to the U.S. Arctic Ocean | 19,126 |
| Minke whale | *Balaenoptera acutorostrata* | Extralimital | Mostly summer | North Pacific Ocean | 810-1,003 |
| Humpback whale (Central North Pacific stock)* | *Megaptera novaeangliae* | Extralimital | Mostly summer | North Pacific Ocean | 21,063 |
| **Pinnipeds** | | | | | |
| Bearded seal (Beringia distinct population segment) | *Erigathus barbatus* | Common | Spring and summer | Bering, Chukchi, and Beaufort Seas | 155,000 |
| Ringed seal (Arctic stock)* | *Phoca hispida* | Common | Year round | Arctic Ocean | 300,000 |
| Spotted seal | *Phoca largha* | Common | Summer | Japan to U.S. Arctic Ocean | 141,479 |
| Ribbon seal | *Histriophoca fasciata* | Occasional | Summer | Arctic Ocean | 49,000 |

*Endangered, threatened, or species of concern under the Endangered Species Act (ESA); Depleted under the MMPA

The highlighted (grayed out) species in Table 2 are so rarely sighted in the proposed project area that take is unlikely. Minke whales are relatively common in the Bering and southern Chukchi Seas and have recently also been sighted in the northeastern Chukchi Sea (Aerts *et al.,* 2013; Clarke *et al.,* 2013). Minke whales are rare in the Beaufort Sea. They have not been reported in the Beaufort Sea during the Bowhead Whale Aerial Survey Project/Aerial Surveys of Arctic Marine Mammals (BWASP/ASAMM) surveys (Clarke *et al.,* 2011, 2012; 2013; Monnet and Treacy, 2005), and there was only one observation in 2007 during vessel-based surveys in the region (Funk *et al.,* 2010). Humpback whales have not generally been found in the Arctic Ocean. However, subsistence hunters have spotted humpback whales in low numbers around Barrow, and there have been several confirmed sightings of humpback whales in the northeastern Chukchi Sea in recent years (Aerts *et al.,* 2013; Clarke *et al.,* 2013). The first confirmed sighting of a humpback whale in the Beaufort Sea was recorded in August 2007 (Hashagen *et al.,* 2009), when a cow and calf were observed 54 mi east of Point Barrow. No additional sightings have been documented in the

Beaufort Sea. Narwhal are common in the waters of northern Canada, west Greenland, and in the European Arctic, but rarely occur in the Beaufort Sea (COSEWIC, 2004). Only a handful of sightings have occurred in Alaskan waters (Allen and Angliss, 2013). These three species are not considered further in this proposed IHA notice. Both the walrus and the polar bear could occur in the U.S. Beaufort Sea; however, these species are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this Notice of Proposed IHA.

The Beaufort Sea is a main corridor of the bowhead whale migration route. The main migration periods occur in spring from April to June and in fall from late August/early September through October to early November. During the fall migration, several locations in the U.S. Beaufort Sea serve as feeding grounds for bowhead whales. Small numbers of bowhead whales that remain in the U.S. Arctic Ocean during summer also feed in these areas. The U.S. Beaufort Sea is not a main feeding or calving area for any other cetacean species. Ringed seals breed and pup in the Beaufort Sea; however, this does not occur during the summer or early fall. Further information on the biology and local distribution of these species can be found in Hilcorp's application (see **ADDRESSES**) and the NMFS Marine Mammal Stock Assessment Reports, which are available online at: *http://www.nmfs.noaa.gov/pr/species/.*

**Potential Effects of the Specified Activity on Marine Mammals**

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.,* sonar sources and vessel movement) have been observed to or are thought to impact marine mammals. This section may include a discussion of known effects that do not rise to the level of an MMPA take (for example, with acoustics, we may include a discussion of studies that showed animals not reacting at all to sound or exhibiting barely measurable avoidance). The discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of a take. This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented or how either of those will shape the anticipated impacts from this specific activity. The ''Estimated Take by Incidental Harassment'' section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis'' section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, the ''Proposed Mitigation'' section, and the ''Anticipated Effects on Marine Mammal Habitat'' section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

*Background on Sound*

Sound is a physical phenomenon consisting of minute vibrations that travel through a medium, such as air or water, and is generally characterized by several variables. Frequency describes the sound's pitch and is measured in hertz (Hz) or kilohertz (kHz), while sound level describes the sound's intensity and is measured in decibels (dB). Sound level increases or decreases exponentially with each dB of change. The logarithmic nature of the scale means that each 10-dB increase is a 10-fold increase in acoustic power (and a 20-dB increase is then a 100-fold increase in power). A 10-fold increase in acoustic power does not mean that the sound is perceived as being 10 times louder, however. Sound levels are compared to a reference sound pressure (micro-Pascal) to identify the medium. For air and water, these reference pressures are ''re: 20 μPa'' and ''re: 1 μPa,'' respectively. Root mean square (RMS) is the quadratic mean sound pressure over the duration of an impulse. RMS is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1975). RMS accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels. This measurement is often used in the context of discussing behavioral effects, in part, because behavioral effects, which often result from auditory cues, may be better expressed through averaged units rather than by peak pressures.

*Acoustic Impacts*

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been derived using auditory evoked potentials, anatomical modeling, and other data, Southall *et al.* (2007) designate ''functional hearing groups'' for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- Low frequency cetaceans (13 species of mysticetes): Functional hearing is estimated to occur between approximately 7 Hz and 30 kHz;
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High frequency cetaceans (eight species of true porpoises, six species of river dolphins, Kogia, the franciscana, and four species of cephalorhynchids): Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz;
- Phocid pinnipeds in water: Functional hearing is estimated to occur between approximately 75 Hz and 100 kHz; and
- Otariid pinnipeds in water: Functional hearing is estimated to occur between approximately 100 Hz and 40 kHz.

As mentioned previously in this document, six marine mammal species (three cetaceans and three phocid pinnipeds) may occur in the proposed shallow hazard survey area. Of the three cetacean species likely to occur in the proposed project area and for which take is requested, two are classified as low-frequency cetaceans (*i.e.,* bowhead and gray whales), the beluga whale is classified as mid-frequency cetacean (Southall *et al.,* 2007). A species functional hearing group is a consideration when we analyze the effects of exposure to sound on marine mammals.

Although the analysis of impacts of underwater sound on marine mammals described below heavily based on studies from seismic airgun noises, Hilcorp's proposed shallow geohazard survey does not plan to use airguns. Therefore, the potential impacts to marine mammals are expected to be much lower. The reason that the analysis includes airgun impact research is because there are few studies on impacts of marine mammals from

marine surveys conducted by sonar equipment.

1. Tolerance

Numerous studies have shown that underwater sounds from industry activities are often readily detectable by marine mammals in the water at distances of many kilometers. Numerous studies have also shown that marine mammals at distances more than a few kilometers away often show no apparent response to industry activities of various types (Miller *et al.,* 2005; Bain and Williams, 2006). This is often true even in cases when the sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales, toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to underwater sound such as airgun pulses or vessels under some conditions, at other times mammals of all three types have shown no overt reactions (*e.g.,* Malme *et al.,* 1986; Richardson *et al.,* 1995). Weir (2008) observed marine mammal responses to seismic pulses from a 24 airgun array firing a total volume of either 5,085 $in^3$ or 3,147 $in^3$ in Angolan waters between August 2004 and May 2005. Weir recorded a total of 207 sightings of humpback whales (n = 66), sperm whales (n = 124), and Atlantic spotted dolphins (n = 17) and reported that there were no significant differences in encounter rates (sightings/hr) for humpback and sperm whales according to the airgun array's operational status (*i.e.,* active versus silent). However, the current geohazard survey will not use airguns. In general, pinnipeds and small odontocetes seem to be more tolerant of exposure to some types of underwater sound than are baleen whales. Richardson *et al.* (1995) found that vessel noise does not seem to strongly affect pinnipeds that are already in the water. Richardson *et al.* (1995) went on to explain that seals on haul-outs sometimes respond strongly to the presence of vessels and at other times appear to show considerable tolerance of vessels.

2. Masking

Masking is the obscuring of sounds of interest by other sounds, often at similar frequencies. Marine mammals use acoustic signals for a variety of purposes, which differ among species, but include communication between individuals, navigation, foraging, reproduction, avoiding predators, and learning about their environment (Erbe and Farmer, 2000). Masking, or auditory interference, generally occurs when sounds in the environment are louder than, and of a similar frequency as, auditory signals an animal is trying to receive. Masking is a phenomenon that affects animals that are trying to receive acoustic information about their environment, including sounds from other members of their species, predators, prey, and sounds that allow them to orient in their environment. Masking these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations.

Masking occurs when anthropogenic sounds and signals (that the animal utilizes) overlap at both spectral and temporal scales. For the sonar sound generated from the proposed shallow geohazard survey, sound will consist of broadband (2–24 kHz) pulses with extremely short durations (less than one second). There is little concern regarding masking near the sound source due to the brief duration of these pulses and relatively longer silence between the pulses. However, at long distances (over tens of kilometers away), due to multipath propagation and reverberation, the durations of airgun pulses can be ''stretched'' to seconds with long decays (Madsen *et al.,* 2006), although the intensity of the sound is greatly reduced.

3. Behavioral Disturbance

Marine mammals may behaviorally react when exposed to anthropogenic sound. These behavioral reactions are often shown as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses (*e.g.,* pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification have the potential to be biologically significant if the change affects growth, survival, or reproduction. Examples of significant behavioral modifications include:

- Drastic change in diving/surfacing patterns (such as those thought to be causing beaked whale stranding due to exposure to military mid-frequency tactical sonar);
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cessation of feeding or social interaction.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography, current activity, reproductive state) and is also difficult to predict (Gordon *et al.,* 2004; Southall *et al.,* 2007; Ellison *et al.,* 2011).

*Mysticetes:* Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable. Whales are often reported to show no overt reactions to pulses from large arrays of airguns at distances beyond a few kilometers, even though the airgun pulses remain well above ambient noise levels out to much greater distances (Miller *et al.,* 2005). However, baleen whales exposed to strong noise pulses often react by deviating from their normal migration route (Richardson *et al.,* 1999). Migrating gray and bowhead whales were observed avoiding the sound source by displacing their migration route to varying degrees but within the natural boundaries of the migration corridors (Schick and Urban, 2000; Richardson *et al.,* 1999). Baleen whale responses to pulsed sound however may depend on the type of activity in which the whales are engaged. Some evidence suggests that feeding bowhead whales may be more tolerant of underwater sound than migrating bowheads (Miller *et al.,* 2005; Lyons *et al.,* 2009; Christie *et al.,* 2010).

Results of studies of gray, bowhead, and humpback whales have determined that received levels of pulses in the 160–170 dB re 1 μPa rms range seem to cause obvious avoidance behavior in a substantial fraction of the animals exposed. In many areas, seismic pulses from large arrays of airguns diminish to those levels at distances ranging from 2.8–9 mi (4.5–14.5 km) from the source. Baleen whales within those distances may show avoidance or other strong disturbance reactions to the airgun array. Subtle behavioral changes sometimes become evident at somewhat lower received levels, and recent studies have shown that some species of baleen whales, notably bowhead and humpback whales, at times show strong avoidance at received levels lower than 160–170 dB re 1 μPa rms. Bowhead whales migrating west across the Alaskan Beaufort Sea in autumn, in particular, are unusually responsive, with avoidance occurring out to distances of 12.4–18.6 mi (20–30 km) from a medium-sized airgun source (Miller *et al.,* 1999; Richardson *et al.,* 1999). However, more recent research

on bowhead whales (Miller *et al.,* 2005) corroborates earlier evidence that, during the summer feeding season, bowheads are not as sensitive to seismic sources. In summer, bowheads typically begin to show avoidance reactions at a received level of about 160–170 dB re 1 μPa rms (Richardson *et al.,* 1986; Ljungblad *et al.,* 1988; Miller *et al.,* 2005).

Malme *et al.* (1986) studied the responses of feeding eastern gray whales to pulses from a single 100 $in^3$ airgun off St. Lawrence Island in the northern Bering Sea. They estimated, based on small sample sizes, that 50% of feeding gray whales ceased feeding at an average received pressure level of 173 dB re 1 μPa on an (approximate) rms basis, and that 10% of feeding whales interrupted feeding at received levels of 163 dB. Those findings were generally consistent with the results of experiments conducted on larger numbers of gray whales that were migrating along the California coast and on observations of the distribution of feeding Western Pacific gray whales off Sakhalin Island, Russia, during a seismic survey (Yazvenko *et al.,* 2007).

Data on short-term reactions (or lack of reactions) of cetaceans to impulsive noises do not necessarily provide information about long-term effects. While it is not certain whether impulsive noises affect reproductive rate or distribution and habitat use in subsequent days or years, certain species have continued to use areas ensonified by airguns and have continued to increase in number despite successive years of anthropogenic activity in the area. Gray whales continued to migrate annually along the west coast of North America despite intermittent seismic exploration and much ship traffic in that area for decades (Appendix A in Malme *et al.,* 1984). Bowhead whales continued to travel to the eastern Beaufort Sea each summer despite seismic exploration in their summer and autumn range for many years (Richardson *et al.,* 1987). Populations of both gray whales and bowhead whales grew substantially during this time. In any event, the proposed survey will occur in summer (July through late August) when most bowhead whales are commonly feeding in the Mackenzie River Delta, Canada.

*Odontocetes:* Few systematic data are available describing reactions of toothed whales to noise pulses. However, systematic work on sperm whales is underway, and there is an increasing amount of information about responses of various odontocetes to seismic surveys based on monitoring studies (*e.g.,* Stone, 2003). Miller *et al.* (2009) conducted at-sea experiments where reactions of sperm whales were monitored through the use of controlled sound exposure experiments from large airgun arrays consisting of 20-guns and 31-guns. Of 8 sperm whales observed, none changed their behavior when exposed to either a ramp-up at 4–8 mi (7–13 km) or full array exposures at 0.6–8 mi (1–13 km).

Seismic operators and marine mammal observers sometimes see dolphins and other small toothed whales near operating airgun arrays, but, in general, there seems to be a tendency for most delphinids to show some limited avoidance of seismic vessels operating large airgun systems. However, some dolphins seem to be attracted to the seismic vessel and floats, and some ride the bow wave of the seismic vessel even when large arrays of airguns are firing. Nonetheless, there have been indications that small toothed whales sometimes move away or maintain a somewhat greater distance from the vessel when a large array of airguns is operating than when it is silent (*e.g.,* 1998; Stone, 2003). The beluga may be a species that (at least in certain geographic areas) shows long-distance avoidance of seismic vessels. Aerial surveys during seismic operations in the southeastern Beaufort Sea recorded much lower sighting rates of beluga whales within 10–20 km (6.2–12.4 mi) of an active seismic vessel. These results were consistent with the low number of beluga sightings reported by observers aboard the seismic vessel, suggesting that some belugas might have been avoiding the seismic operations at distances of 10–20 km (6.2–12.4 mi) (Miller *et al.,* 2005).

Captive bottlenose dolphins and (of more relevance in this project) beluga whales exhibit changes in behavior when exposed to strong pulsed sounds similar in duration to those typically used in seismic surveys (Finneran *et al.,* 2002, 2005). However, the animals tolerated high received levels of sound (pk–pk level >200 dB re 1 μPa) before exhibiting aversive behaviors.

Observers stationed on seismic vessels operating off the United Kingdom from 1997–2000 have provided data on the occurrence and behavior of various toothed whales exposed to seismic pulses (Stone, 2003; Gordon *et al.,* 2004). Killer whales were found to be significantly farther from large airgun arrays during periods of shooting compared with periods of no shooting. The displacement of the median distance from the array was approximately 0.5 km (0.3 mi) or more. Killer whales also appear to be more tolerant of seismic shooting in deeper water.

Reactions of toothed whales to large arrays of airguns are variable and, at least for delphinids, seem to be confined to a smaller radius than has been observed for mysticetes. However, based on the limited existing evidence, belugas should not be grouped with delphinids in the ''less responsive'' category.

*Pinnipeds:* Pinnipeds are not likely to show a strong avoidance reaction to the airgun sources proposed for use. Visual monitoring from seismic vessels has shown only slight (if any) avoidance of airguns by pinnipeds and only slight (if any) changes in behavior. Monitoring work in the Alaskan Beaufort Sea during 1996–2001 provided considerable information regarding the behavior of Arctic ice seals exposed to seismic pulses (Harris *et al.,* 2001; Moulton and Lawson, 2002). These seismic projects usually involved arrays of 6 to 16 airguns with total volumes of 560 to 1,500 $in^3$. The combined results suggest that some seals avoid the immediate area around seismic vessels. In most survey years, ringed seal sightings tended to be farther away from the seismic vessel when the airguns were operating than when they were not (Moulton and Lawson, 2002). However, these avoidance movements were relatively small, on the order of 100 m (328 ft) to a few hundreds of meters, and many seals remained within 100–200 m (328–656 ft) of the trackline as the operating airgun array passed by. Seal sighting rates at the water surface were lower during airgun array operations than during no-airgun periods in each survey year except 1997. Similarly, seals are often very tolerant of pulsed sounds from seal-scaring devices (Richardson *et al.,* 1995). However, initial telemetry work suggests that avoidance and other behavioral reactions by two other species of seals to small airgun sources may at times be stronger than evident to date from visual studies of pinniped reactions to airguns (Thompson *et al.,* 1998). Even if reactions of the species occurring in the present study area are as strong as those evident in the telemetry study, reactions are expected to be confined to relatively small distances and durations, with no long-term effects on pinniped individuals or populations.

4. Threshold Shift (Noise-Induced Loss of Hearing)

When animals exhibit reduced hearing sensitivity (*i.e.,* sounds must be louder for an animal to detect them) following exposure to an intense sound or sound for long duration, it is referred

to as a noise-induced threshold shift (TS). An animal can experience temporary threshold shift (TTS) or permanent threshold shift (PTS). TTS can last from minutes or hours to days (*i.e.,* there is complete recovery), can occur in specific frequency ranges (*i.e.,* an animal might only have a temporary loss of hearing sensitivity between the frequencies of 1 and 10 kHz), and can be of varying amounts (for example, an animal's hearing sensitivity might be reduced initially by only 6 dB or reduced by 30 dB). PTS is permanent, but some recovery is possible. PTS can also occur in a specific frequency range and amount as mentioned above for TTS.

The following physiological mechanisms are thought to play a role in inducing auditory TS: Effects to sensory hair cells in the inner ear that reduce their sensitivity, modification of the chemical environment within the sensory cells, residual muscular activity in the middle ear, displacement of certain inner ear membranes, increased blood flow, and post-stimulatory reduction in both efferent and sensory neural output (Southall *et al.,* 2007). The amplitude, duration, frequency, temporal pattern, and energy distribution of sound exposure all can affect the amount of associated TS and the frequency range in which it occurs. As amplitude and duration of sound exposure increase, so, generally, does the amount of TS, along with the recovery time. For intermittent sounds, less TS could occur than compared to a continuous exposure with the same energy (some recovery could occur between intermittent exposures depending on the duty cycle between sounds) (Ward, 1997). For example, one short but loud (higher SPL) sound exposure may induce the same impairment as one longer but softer sound, which in turn may cause more impairment than a series of several intermittent softer sounds with the same total energy (Ward, 1997). Additionally, though TTS is temporary, prolonged exposure to sounds strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold, can cause PTS, at least in terrestrial mammals.

PTS is considered auditory injury (Southall *et al.,* 2007). Irreparable damage to the inner or outer cochlear hair cells may cause PTS; however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.,* 2007).

Although the published body of scientific literature contains numerous theoretical studies and discussion papers on hearing impairments that can occur with exposure to a loud sound, only a few studies provide empirical information on the levels at which noise-induced loss in hearing sensitivity occurs in nonhuman animals. For marine mammals, published data are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise (Finneran *et al.,* 2000, 2002, 2003, 2005, 2007; Finneran and Schlundt, 2010; Lucke *et al.,* 2009; Mooney *et al.,* 2009; Popov *et al.,* 2011a, 2011b; Kastelein *et al.,* 2012a; Schlundt *et al.,* 2006; Nachtigall *et al.,* 2003, 2004). For pinnipeds in water, data are limited to measurements of TTS in harbor seals, an elephant seal, and California sea lions (Kastak *et al.,* 2005; Kastelein *et al.,* 2012b).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. Also, depending on the degree and frequency range, the effects of PTS on an animal could range in severity, although it is considered generally more serious because it is a permanent condition. Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

5. Non-Auditory Physical Effects

Non-auditory physical effects might occur in marine mammals exposed to strong underwater sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. Some marine mammal species (*i.e.,* beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds.

Classic stress responses begin when an animal's central nervous system perceives a potential threat to its homeostasis. That perception triggers stress responses regardless of whether a stimulus actually threatens the animal; the mere perception of a threat is sufficient to trigger a stress response (Moberg, 2000; Sapolsky *et al.,* 2005; Seyle, 1950). Once an animal's central nervous system perceives a threat, it mounts a biological response or defense that consists of a combination of the four general biological defense responses: behavioral responses; autonomic nervous system responses; neuroendocrine responses; or immune responses.

In the case of many stressors, an animal's first and most economical (in terms of biotic costs) response is behavioral avoidance of the potential stressor or avoidance of continued exposure to a stressor. An animal's second line of defense to stressors involves the sympathetic part of the autonomic nervous system and the classical ''fight or flight'' response, which includes the cardiovascular system, the gastrointestinal system, the exocrine glands, and the adrenal medulla to produce changes in heart rate, blood pressure, and gastrointestinal activity that humans commonly associate with ''stress.'' These responses have a relatively short duration and may or may not have significant long-term effects on an animal's welfare.

An animal's third line of defense to stressors involves its neuroendocrine or sympathetic nervous systems; the system that has received the most study has been the hypothalmus-pituitary-adrenal system (also known as the HPA axis in mammals or the hypothalamus-pituitary-interrenal axis in fish and some reptiles). Unlike stress responses associated with the autonomic nervous system, virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction (Moberg, 1987), altered metabolism (Elasser *et al.,* 2000), reduced immune competence (Blecha, 2000), and behavioral disturbance. Increases in the circulation of glucocorticosteroids (cortisol, corticosterone, and aldosterone in marine mammals; see

Romano *et al.,* 2004) have been equated with stress for many years.

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and distress is the biotic cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose a risk to the animal's welfare. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other biotic functions, which impair those functions that experience the diversion. For example, when mounting a stress response diverts energy away from growth in young animals, those animals may experience stunted growth. When mounting a stress response diverts energy from a fetus, an animal's reproductive success and fitness will suffer. In these cases, the animals will have entered a pre-pathological or pathological state which is called ''distress'' (sensu Seyle, 1950) or ''allostatic loading'' (sensu McEwen and Wingfield, 2003). This pathological state will last until the animal replenishes its biotic reserves sufficient to restore normal function. Note that these examples involved a long-term (days or weeks) stress response exposure to stimuli.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses have also been documented fairly well through controlled experiment; because this physiology exists in every vertebrate that has been studied, it is not surprising that stress responses and their costs have been documented in both laboratory and free-living animals (for examples see, Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005; Reneerkens *et al.,* 2002; Thompson and Hamer, 2000). Although no information has been collected on the physiological responses of marine mammals to anthropogenic sound exposure, studies of other marine animals and terrestrial animals would lead us to expect some marine mammals to experience physiological stress responses and, perhaps, physiological responses that would be classified as ''distress'' upon exposure to anthropogenic sounds.

For example, Jansen (1998) reported on the relationship between acoustic exposures and physiological responses that are indicative of stress responses in humans (*e.g.,* elevated respiration and increased heart rates). Jones (1998) reported on reductions in human performance when faced with acute, repetitive exposures to acoustic disturbance. Trimper *et al.* (1998) reported on the physiological stress responses of osprey to low-level aircraft noise while Krausman *et al.* (2004) reported on the auditory and physiology stress responses of endangered Sonoran pronghorn to military overflights. Smith *et al.* (2004a, 2004b) identified noise-induced physiological transient stress responses in hearing-specialist fish (*i.e.,* goldfish) that accompanied short- and long-term hearing losses. Welch and Welch (1970) reported physiological and behavioral stress responses that accompanied damage to the inner ears of fish and several mammals.

Hearing is one of the primary senses marine mammals use to gather information about their environment and communicate with conspecifics. Although empirical information on the relationship between sensory impairment (TTS, PTS, and acoustic masking) on marine mammals remains limited, we assume that reducing a marine mammal's ability to gather information about its environment and communicate with other members of its species would induce stress, based on data that terrestrial animals exhibit those responses under similar conditions (NRC, 2003) and because marine mammals use hearing as their primary sensory mechanism. Therefore, we assume that acoustic exposures sufficient to trigger onset PTS or TTS would be accompanied by physiological stress responses. More importantly, marine mammals might experience stress responses at received levels lower than those necessary to trigger onset TTS. Based on empirical studies of the time required to recover from stress responses (Moberg, 2000), NMFS also assumes that stress responses could persist beyond the time interval required for animals to recover from TTS and might result in pathological and pre-pathological states that would be as significant as behavioral responses to TTS.

Resonance effects (Gentry, 2002) and direct noise-induced bubble formations (Crum *et al.,* 2005) are implausible in the case of exposure to an impulsive broadband source like an airgun array. If seismic surveys disrupt diving patterns of deep-diving species, this might result in bubble formation and a form of the bends, as speculated to occur in beaked whales exposed to sonar. However, there is no specific evidence of this upon exposure to low-intensity civilian sonar pulses. Additionally, no beaked whale species occur in the proposed project area.

In general, very little is known about the potential for strong, anthropogenic underwater sounds to cause non-auditory physical effects in marine mammals. Such effects, if they occur at all, would presumably be limited to short distances and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.,* 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. There is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of airguns, which are not proposed for use during this program. In addition, marine mammals that show behavioral avoidance of industry activities, including bowheads, belugas, and some pinnipeds, are especially unlikely to incur non-auditory impairment or other physical effects.

6. Stranding and Mortality

Marine mammals close to underwater detonations of high explosive can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.,* 1993; Ketten, 1995). Airgun pulses are less energetic and their peak amplitudes have slower rise times. To date, there is no evidence that serious injury, death, or stranding by marine mammals can occur from exposure to airgun pulses, even in the case of large airgun arrays. Additionally, Hilcorp's project will use low-intensity sonar equipment in shallow water. NMFS does not expect any marine mammals will incur injury or mortality in the shallow waters off Beaufort Sea or strand as a result of the proposed geohazard survey.

*Vessel Impacts*

Vessel activity and noise associated with vessel activity will temporarily increase in the action area during Hilcorp's shallow geohazard survey as a result of the operation of 1–2 vessels. To minimize the effects of vessels and noise associated with vessel activity, Hilcorp will alter speed if a marine mammal gets too close to a vessel. In addition, source vessels will be operating at slow speed (4–5 knots) when conducting surveys. Marine mammal monitoring observers will alert vessel captains as animals are detected to ensure safe and effective measures are applied to avoid coming into direct contact with marine mammals. Therefore, NMFS neither anticipates nor

authorizes takes of marine mammals from ship strikes.

McCauley *et al.* (1996) reported several cases of humpback whales responding to vessels in Hervey Bay, Australia. Results indicated clear avoidance at received levels between 118 to 124 dB in three cases for which response and received levels were observed/measured.

Palka and Hammond (2001) analyzed line transect census data in which the orientation and distance off transect line were reported for large numbers of minke whales. The authors developed a method to account for effects of animal movement in response to sighting platforms. Minor changes in locomotion speed, direction, and/or diving profile were reported at ranges from 1,847 to 2,352 ft (563 to 717 m) at received levels of 110 to 120 dB.

Odontocetes, such as beluga whales, killer whales, and harbor porpoises, often show tolerance to vessel activity; however, they may react at long distances if they are confined by ice, shallow water, or were previously harassed by vessels (Richardson *et al.,* 1995). Beluga whale response to vessel noise varies greatly from tolerance to extreme sensitivity depending on the activity of the whale and previous experience with vessels (Richardson *et al.,* 1995). Reactions to vessels depends on whale activities and experience, habitat, boat type, and boat behavior (Richardson *et al.,* 1995) and may include behavioral responses, such as altered headings or avoidance (Blane and Jaakson, 1994; Erbe and Farmer, 2000); fast swimming; changes in vocalizations (Lesage *et al.,* 1999; Scheifele *et al.,* 2005); and changes in dive, surfacing, and respiration patterns.

There are few data published on pinniped responses to vessel activity, and most of the information is anecdotal (Richardson *et al.,* 1995). Generally, sea lions in water show tolerance to close and frequently approaching vessels and sometimes show interest in fishing vessels. They are less tolerant when hauled out on land; however, they rarely react unless the vessel approaches within 100–200 m (Richardson *et al.,* 1995).

The addition of the vessels and noise due to vessel operations associated with the shallow geohazard survey is not expected to have effects that could cause significant or long-term consequences for individual marine mammals or their populations.

**Anticipated Effects on Marine Mammal Habitat**

The primary potential impacts to marine mammal habitat and other marine species are associated with elevated sound levels produced by airguns and other active acoustic sources. However, other potential impacts to the surrounding habitat from physical disturbance are also possible. This section describes the potential impacts to marine mammal habitat from the specified activity. Because the marine mammals in the area feed on fish and/or invertebrates there is also information on the species typically preyed upon by the marine mammals in the area.

With regard to fish as a prey source for odontocetes and seals, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.,* 1981) and possibly avoid predators (Wilson and Dill, 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins, 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

Fishes produce sounds that are associated with behaviors that include territoriality, mate search, courtship, and aggression. It has also been speculated that sound production may provide the means for long distance communication and communication under poor underwater visibility conditions (Zelick *et al.,* 1999), although the fact that fish communicate at low-frequency sound levels where the masking effects of ambient noise are naturally highest suggests that very long distance communication would rarely be possible. Fishes have evolved a diversity of sound generating organs and acoustic signals of various temporal and spectral contents. Fish sounds vary in structure, depending on the mechanism used to produce them (Hawkins, 1993). Generally, fish sounds are predominantly composed of low frequencies (less than 3 kHz).

Since objects in the water scatter sound, fish are able to detect these objects through monitoring the ambient noise. Therefore, fish are probably able to detect prey, predators, conspecifics, and physical features by listening to environmental sounds (Hawkins, 1981). There are two sensory systems that enable fish to monitor the vibration-based information of their surroundings. The two sensory systems, the inner ear and the lateral line, constitute the acoustico-lateralis system.

Although the hearing sensitivities of very few fish species have been studied to date, it is becoming obvious that the intra- and inter-specific variability is considerable (Coombs, 1981). Nedwell *et al.* (2004) compiled and published available fish audiogram information. A noninvasive electrophysiological recording method known as auditory brainstem response is now commonly used in the production of fish audiograms (Yan, 2004). Generally, most fish have their best hearing in the low-frequency range (*i.e.,* less than 1 kHz). Even though some fish are able to detect sounds in the ultrasonic frequency range, the thresholds at these higher frequencies tend to be considerably higher than those at the lower end of the auditory frequency range.

Literature relating to the impacts of sound on marine fish species can be divided into the following categories: (1) Pathological effects; (2) physiological effects; and (3) behavioral effects. Pathological effects include lethal and sub-lethal physical damage to fish; physiological effects include primary and secondary stress responses; and behavioral effects include changes in exhibited behaviors of fish. Behavioral changes might be a direct reaction to a detected sound or a result of the anthropogenic sound masking natural sounds that the fish normally detect and to which they respond. The three types of effects are often interrelated in complex ways. For example, some physiological and behavioral effects could potentially lead to the ultimate pathological effect of mortality. Hastings and Popper (2005) reviewed what is known about the effects of sound on fishes and identified studies needed to address areas of uncertainty relative to measurement of sound and the responses of fishes. Popper *et al.* (2003/2004) also published a paper that reviews the effects of anthropogenic sound on the behavior and physiology of fishes.

Potential effects of exposure to sound on marine fish include TTS, physical damage to the ear region, physiological stress responses, and behavioral responses such as startle response, alarm response, avoidance, and perhaps lack of response due to masking of acoustic cues. Most of these effects appear to be either temporary or intermittent and therefore probably do not significantly impact the fish at a population level. The studies that resulted in physical damage to the fish ears used noise exposure levels and durations that were far more extreme than would be encountered under conditions similar to those expected during Hilcorp's proposed survey.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about

20 dB above the detection level of 120 dB (Ona, 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.,* 1993). In general, fish react more strongly to pulses of sound rather than a continuous signal (Blaxter *et al.,* 1981), such as the type of sound that will be produced by the drillship, and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

Investigations of fish behavior in relation to vessel noise (Olsen *et al.,* 1983; Ona, 1988; Ona and Godo, 1990) have shown that fish react when the sound from the engines and propeller exceeds a certain level. Avoidance reactions have been observed in fish such as cod and herring when vessels approached close enough that received sound levels are 110 dB to 130 dB (Nakken, 1992; Olsen, 1979; Ona and Godo, 1990; Ona and Toresen, 1988). However, other researchers have found that fish such as polar cod, herring, and capeline are often attracted to vessels (apparently by the noise) and swim toward the vessel (Rostad *et al.,* 2006). Typical sound source levels of vessel noise in the audible range for fish are 150 dB to 170 dB (Richardson *et al.,* 1995a). In calm weather, ambient noise levels in audible parts of the spectrum lie between 60 dB to 100 dB.

Short, sharp sounds can cause overt or subtle changes in fish behavior. Chapman and Hawkins (1969) tested the reactions of whiting (hake) in the field to an airgun. When the airgun was fired, the fish dove from 82 to 180 ft (25 to 55 m) depth and formed a compact layer. The whiting dove when received sound levels were higher than 178 dB re 1 μPa (Pearson *et al.,* 1992).

Pearson *et al.* (1992) conducted a controlled experiment to determine effects of strong noise pulses on several species of rockfish off the California coast. They used an airgun with a source level of 223 dB re 1 μPa. They noted:

- Startle responses at received levels of 200–205 dB re 1 μPa and above for two sensitive species, but not for two other species exposed to levels up to 207 dB;
- Alarm responses at 177–180 dB for the two sensitive species, and at 186 to 199 dB for other species;
- An overall threshold for the above behavioral response at about 180 dB;
- An extrapolated threshold of about 161 dB for subtle changes in the behavior of rockfish; and
- A return to pre-exposure behaviors within the 20–60 minute exposure period.

In summary, fish often react to sounds, especially strong and/or intermittent sounds of low frequency. Sound pulses at received levels of 160 dB re 1 μPa may cause subtle changes in behavior. Pulses at levels of 180 dB may cause noticeable changes in behavior (Chapman and Hawkins, 1969; Pearson *et al.,* 1992; Skalski *et al.,* 1992). It also appears that fish often habituate to repeated strong sounds rather rapidly, on time scales of minutes to an hour. However, the habituation does not endure, and resumption of the strong sound source may again elicit disturbance responses from the same fish.

Some of the fish species found in the Arctic are prey sources for odontocetes and pinnipeds. A reaction by fish to sounds produced by Hilcorp's proposed survey would only be relevant to marine mammals if it caused concentrations of fish to vacate the area. Pressure changes of sufficient magnitude to cause that type of reaction would probably occur only very close to the sound source, if any would occur at all. Impacts on fish behavior are predicted to be inconsequential. Thus, feeding odontocetes and pinnipeds would not be adversely affected by this minimal loss or scattering, if any, of reduced prey abundance.

Some mysticetes, including bowhead whales, feed on concentrations of zooplankton. Some feeding bowhead whales may occur in the Alaskan Beaufort Sea in July and August, but feeding bowheads are more likely to occur in the area after the cessation of survey operations. Reactions of zooplankton to sound are, for the most part, not known. Their ability to move significant distances is limited or nil, depending on the type of zooplankton. Behavior of zooplankters is not expected to be affected by the survey. These animals have exoskeletons and no air bladders. Many crustaceans can make sounds, and some crustacea and other invertebrates have some type of sound receptor. A reaction by zooplankton to sounds produced by the seismic survey would only be relevant to whales if it caused concentrations of zooplankton to scatter. Pressure changes of sufficient magnitude to cause that type of reaction would probably occur only very close to the sound source, if any would occur at all. Impacts on zooplankton behavior are predicted to be inconsequential. Thus, feeding mysticetes would not be adversely affected by this minimal loss or scattering, if any, of reduced zooplankton abundance.

Based on the preceding discussion, the proposed activity is not expected to have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or their populations.

**Proposed Mitigation**

In order to issue an incidental take authorization (ITA) under sections 101(a)(5)(A) and (D) of the MMPA, NMFS must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant). This section summarizes the contents of Hilcorp's Marine Mammal Monitoring and Mitigation Plan (4MP). Later in this document in the ''Proposed Incidental Harassment Authorization'' section, NMFS lays out the proposed conditions for review, as they would appear in the final IHA (if issued).

Hilcorp submitted a 4MP as part of its application (see ADDRESSES). Hilcorp's planned shallow geohazard survey incorporates both design features and operational procedures for minimizing potential impacts on marine mammals and on subsistence hunts. The 4MP is a combination of active monitoring in the area of operations and the implementation of mitigation measures designed to minimize project impacts to marine resources. Monitoring will provide information on marine mammals potentially affected by exploration activities, in addition to facilitating real time mitigation to prevent injury of marine mammals by industrial sounds or activities.

*Vessel Related Mitigation Measures*

The general mitigation measures apply to all vessels that are part of the Foggy Island Bay sonar survey. The source vessel will operate under an additional set of specific mitigation measures during operations.

- To minimize collision risk with marine mammals, vessels shall not be operated at speeds that would make collisions likely. When weather conditions require, such as when visibility drops, vessels shall adjust speed accordingly to avoid the likelihood of marine mammal collisions.
- Vessel operators shall check the waters immediately adjacent to a vessel to ensure that no marine mammals will be injured when the vessel's propellers (or screws) are engaged.

• Vessel operators shall avoid concentrations or groups of whales and vessels shall not be operated in a way that separates members of a group. In proximity of feeding whales or aggregations, vessel speed shall be less than 10 knots.

• When within 900 ft. (300 m) of whales vessel operators shall take every effort and precaution to avoid harassment of these animals by:

○ Reducing speed and steering around (groups of) whales if circumstances allow, but never cutting off a whale's travel path;

○ Avoiding multiple changes in direction and speed.

• In general, the survey design will start in shallow water and work deeper to mitigate the potential ''herding'' effect.

*Establishing Exclusion and Disturbance Zones*

Under current NMFS guidelines, the ''exclusion zone'' for marine mammal exposure to impulse sources is customarily defined as the area within which received sound levels are ≥180 dB (rms) re 1 μPa for cetaceans and ≥190 dB (rms) re 1 μPa for pinnipeds. These safety criteria are based on an assumption that SPL received at levels lower than these will not injure these animals or impair their hearing abilities, but at higher levels might have some such effects. Disturbance or behavioral effects to marine mammals from underwater sound may occur after exposure to sound at distances greater than the exclusion zones (Richardson *et al.* 1995). Currently, NMFS uses 160 dB (rms) re 1 μPa as the threshold for Level B behavioral harassment from impulse noise.

The sounds generated by the multibeam echosounder and sidescan sonar are outside the hearing range of marine mammals. Sounds generated by the sub-bottom profiler are within the hearing range of all marine mammal species occurring in the area. The distance to 160 dB re 1 μPa (rms) zone of influence (ZOI) is estimated at 30 m (Warner & McCrodan 2011). However, Hilcorp will establish a ZOI of 50 m around all sonar sources for more protective measures. The exclusion zones of all sonar equipment are less than 30 m from the sources.

*Mitigation Measures for Sonar Equipment*

(1) Ramp Up Procedure

A ramp up of the sub-bottom profiler provides a gradual increase in sound levels, and involves a step-wise increase in the number and incremental levels of the sub-bottom profiler firing until the maximum level is achieved. The purpose of a ramp up (or ''soft start'') is to ''warn'' cetaceans and pinnipeds in the vicinity of the survey and to provide time for them to leave the area and thus reducing startling responses from marine mammals.

(2) Shutdown Measures

Although there is no exclusion zone expected from the sonar source operated by Hilcorp during its proposed shallow geohazard survey, Hilcorp proposes to implement shutdown measures when a marine mammals is sighted within the 50 m ZOI during the operation of the sub-bottom profiler.

After showdown for more than 10 minutes, ramp-up shall not start until after the marine mammal is visually seen left the ZOI; or 15 minutes have passed after the last detection of the marine mammal with shorter dive durations (pinnipeds and small odontocetes); or 30 minutes have passed after the last detection of the marine mammal with longer diver durations (mysticetes and large odontocetes, including beluga whales).

(3) Poor Visibility Conditions

If during foggy conditions, heavy snow or rain, or darkness, the full 160 dB ZOI is not visible, sonar equipment cannot commence a ramp-up procedure from a full shut-down. If the sub-bottom profiler has been operational before nightfall or before the onset of poor visibility conditions, it can remain operational throughout the night or poor visibility conditions.

*Mitigation Conclusions*

NMFS has carefully evaluated Hilcorp's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

• The manner in which, and the degree to which, the successful implementation of the measures are expected to minimize adverse impacts to marine mammals;

• The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and

• The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of sub-bottom profiler, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of sub-bottom profiler or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of sub-bottom profiler or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing the severity of harassment takes only).

5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance. Proposed measures to ensure availability of such species or stock for taking for certain subsistence uses are discussed later in this document (see ''Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses'' section).

**Proposed Monitoring and Reporting**

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth, ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Hilcorp submitted a marine mammal monitoring plan as part of the IHA application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period or from the peer review panel (see the ''Monitoring Plan Peer Review'' section later in this document).

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

1. An increase in our understanding of the likely occurrence of marine mammal species in the vicinity of the action, *i.e.,* presence, abundance, distribution, and/or density of species.

2. An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammal species to any of the potential stressor(s) associated with the action (*e.g.* sound or visual stimuli), through better understanding of one or more of the following: the action itself and its environment (*e.g.* sound source characterization, propagation, and ambient noise levels); the affected species (*e.g.* life history or dive pattern); the likely co-occurrence of marine mammal species with the action (in whole or part) associated with specific adverse effects; and/or the likely biological or behavioral context of exposure to the stressor for the marine mammal (*e.g.* age class of exposed animals or known pupping, calving or feeding areas).

3. An increase in our understanding of how individual marine mammals respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level).

4. An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: the long-term fitness and survival of an individual; or the population, species, or stock (*e.g.* through effects on annual rates of recruitment or survival).

5. An increase in our understanding of how the activity affects marine mammal habitat, such as through effects on prey sources or acoustic habitat (*e.g.,* through characterization of longer-term contributions of multiple sound sources to rising ambient noise levels and assessment of the potential chronic effects on marine mammals).

6. An increase in understanding of the impacts of the activity on marine mammals in combination with the impacts of other anthropogenic activities or natural factors occurring in the region.

7. An increase in our understanding of the effectiveness of mitigation and monitoring measures.

8. An increase in the probability of detecting marine mammals (through improved technology or methodology), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals.

*Proposed Monitoring Measures*

Monitoring will provide information on the numbers of marine mammals potentially affected by the exploration operations and facilitate real-time mitigation to prevent injury of marine mammals by industrial sounds or activities. These goals will be accomplished in the Beaufort Sea during 2015 by conducting vessel-based monitoring and passive acoustic monitoring to document marine mammal presence and distribution in the vicinity of the survey area.

Visual monitoring by Protected Species Observers (PSOs) during shallow geohazard survey operations, and periods when these surveys are not occurring, will provide information on the numbers of marine mammals potentially affected by these activities and facilitate real-time mitigation to prevent impacts to marine mammals by industrial sounds or operations. Vessel-based PSOs onboard the survey vessels will record the numbers and species of marine mammals observed in the area and any observable reaction of marine mammals to the survey activities in the Beaufort Sea.

(1) Vessel-Based Monitoring

(A) Protected Species Observers (PSOs)

Vessel-based monitoring for marine mammals will be done by trained PSOs throughout the period of survey activities. The observers will monitor the occurrence of marine mammals near the survey vessel during all daylight periods during operation, and during most daylight periods when operations are not occurring. PSO duties will include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the survey operations; and documenting ''take by harassment.''

Two PSOs will be present on the main sonar vessel. The smaller skiff may only accommodate one at a time. Of these two PSOs, one will be on watch at all times, except during darkness.

PSO teams will consist of Inupiat observers and experienced field biologists. Each vessel will have an experienced field crew leader to supervise the PSO team.

Visual monitoring by the PSOs will be required to meet the following criteria:

- 100% monitoring coverage during all periods of survey operations in daylight;
- Maximum of 4 consecutive hours on watch per PSO; and
- Maximum of 12 hours of watch time per day per PSO.

(B) PSO Qualifications and Training

Lead PSOs will be individuals with experience as observers during recent seismic, site clearance and shallow hazards, and other monitoring projects in Alaska or other offshore areas in recent years. New or inexperienced PSOs will be paired with an experienced PSO or experienced field biologist so that the quality of marine mammal observations and data recording is kept consistent.

Resumes for candidate PSOs will be provided to NMFS for review and acceptance of their qualifications. Inupiat observers will be experienced in the region and familiar with the marine mammals of the area. All observers will complete a training course designed to familiarize individuals with monitoring and data collection procedures.

(C) Marine Mammal Observer Protocol

The PSOs will watch for marine mammals during all periods of source operations and for a minimum of 30 minutes prior to the planned start of sonar operations after an extended shutdown. Marine mammal monitoring shall continue throughout sonar operations and last for 30 minutes after the finish of sonar operations during daylight hours. Hilcorp vessel crew and operations personnel will also watch for marine mammals, as practical, to assist and alert the PSOs for the sub-bottom profiler to be shut down if marine mammals are observed in or about to enter the 50-m ZOI.

PSOs will also perform vessel-based marine mammal monitoring during

vessel transit when the shallow geohazard survey is not being conducted. Marine mammal sighting data collected during the non-survey period will be compared with those during the survey to analyze the effects of the activities.

The PSOs will watch for marine mammals from the best available vantage point on the vessels. The PSOs will scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7 x 50 and 16–40 x 80) and with the naked eye. GPS unit and laptop computer(s) will also be available for PSOs onboard survey vessels.

The observers will give particular attention to the areas within the marine mammal exclusion zones around the source vessels.

When a marine mammal is seen approaching or within the 50-m ZOI, the survey crew will be notified immediately so that mitigation measures called for in the applicable authorization(s) can be implemented.

Information to be recorded by PSOs will include:

- Species, group size, age/size/sex categories (if determinable), physical description of features that were observed or determined not to be present in the case of unknown or unidentified animals;
- Behavior when first sighted and after initial sighting;
- Heading (if consistent), bearing and distance from observer;
- Apparent reaction to activities (*e.g.,* none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace;
- Time, location, speed, and activity of the vessel, sea state, ice cover, visibility, and sun glare; and
- Positions of other vessel(s) (if present) in the vicinity of the observer location.

The vessel's position, speed, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

(2) Acoustic Monitoring

Passive acoustic monitoring (PAM) will be conducted to document ambient noise conditions, to examine the spatial and temporal distribution of marine mammals based on acoustic detections of their vocalizations, and to characterize the long-range propagation of sounds produced during the geohazard survey. The goal of the program is to address knowledge gaps about ambient sound levels and the distributions and migration paths of several marine mammal species including bowhead whales, beluga whales, and seals.

The acoustic data will be collected with Autonomous Multichannel Acoustic Recorder (AMAR) systems deployed on the seabed for an extended period. Two AMARs with different sampling rates will be deployed on the seabed for 3 months. An AMAR with a sampling rate of 64 kHz (24 bits) will be deployed at 500 m from the offshore end of the survey line and will record continuously. A high-frequency AMAR with a sampling rate of 380 kHz (16 bits) will be deployed at 5,000 m from the offshore end of the survey line. This high-frequency AMAR will be operated at 380 kHz (16 bits) for 2 minutes each hour and the rest of the time at 64 kHz (24 bits). The AMARs will be calibrated using pistonphone calibrators immediately before and after each deployment. These calibrations are accurate to less than 0.5 dB absolute.

*Monitoring Plan Peer Review*

The MMPA requires that monitoring plans be independently peer reviewed ''where the proposed activity may affect the availability of a species or stock for taking for subsistence uses'' (16 U.S.C. 1371(a)(5)(D)(ii)(III)). Regarding this requirement, NMFS' implementing regulations state, ''Upon receipt of a complete monitoring plan, and at its discretion, [NMFS] will either submit the plan to members of a peer review panel for review or within 60 days of receipt of the proposed monitoring plan, schedule a workshop to review the plan'' (50 CFR 216.108(d)).

NMFS has established an independent peer review panel to review Hilcorp's 4MP for the proposed shallow geohazard survey in the Beaufort Sea. The panel has met in early March 2015, and provided comments and recommendations to NMFS in April 2015. The full panel report can be viewed on the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

NMFS provided the panel with Hilcorp's IHA application and monitoring plan and asked the panel to answer the following questions:

1. Will the applicant's stated objectives effectively further the understanding of the impacts of their activities on marine mammals and otherwise accomplish the goals stated above? If not, how should the objectives be modified to better accomplish the goals above?

2. Can the applicant achieve the stated objectives based on the methods described in the plan?

3. Are there technical modifications to the proposed monitoring techniques and methodologies proposed by the applicant that should be considered to better accomplish their stated objectives?

4. Are there techniques not proposed by the applicant (*i.e.,* additional monitoring techniques or methodologies) that should be considered for inclusion in the applicant's monitoring program to better accomplish their stated objectives?

5. What is the best way for an applicant to present their data and results (formatting, metrics, graphics, etc.) in the required reports that are to be submitted to NMFS (*i.e.,* 90-day report and comprehensive report)?

The peer-review panel report contains recommendations that the panel members felt were applicable to the Hilcorp' monitoring plans. The panel believes that the objectives for both vessel-based and passive acoustic monitoring are appropriate, and agrees that the objective of real-time mitigation of potential disturbance of marine mammals would be met through visual monitoring. Nevertheless, the panel is concerned that there may also be behavioral effects resulting from the use of single and multi-beam echosounders and side-scan sonar that may warrant real-time mitigation to avoid disturbance, and provide a series of recommendations to improve efficiencies and effectiveness of monitoring and mitigation measures.

Specific recommendations provided by the peer review panel to enhance marine mammal monitoring and reporting measures are:

(1) Deploying an additional observer on the source vessel such that at least two observers are on watch during all daylight hours;

(2) Monitoring for marine mammals also be conducted during non-survey activities to assist in the collection of baseline information from which to analyze the effects of the activities;

(3) Deploying a third autonomous multichannel acoustic recorder (AMAR) and arrange the AMARs in a triangular array, as depicted in Figure 1 of the panel report, with the 500 m AMAR be a high-frequency AMAR, for marine mammal monitoring;

(4) Using AMAR to collect data on cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers;

(5) Ground-truthing data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations and to include error rates for automatic detection to ensure the

accurate classification of vocalizations by species;

(6) Collaborating with other entities collecting data on marine mammal vocalizations in the Beaufort Sea to improve auto-detection and manual capabilities for identifying species in which acoustic data are limited or lacking (*e.g.,* spotted seals); and

(7) Including information from high frequency acoustic recordings in reports to provide a better understanding of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and ⅓ octave bands.

In addition, although not requested by NMFS under the MMPA, the panel also provided several mitigation measures. These recommendations are:

(1) Hilcorp limit operations at night or during periods of low visibility so that marine mammals do not enter the safety zone undetected;

(2) Hilcorp specify that the delay for ramp-up and after a shut-down should be 15 minutes for species with short dive durations (small odontocetes and pinnipeds) and 30 minutes for species with longer diver durations (mysticetes and large odontocetes, including beluga whales);

(3) Additional sound source information from the various active acoustic equipment proposed for the survey be obtained by maneuvering the source vessels over the high frequency AMARs; and

(4) Hilcorp conduct the survey starting closest to shore and proceeding offshore to avoid any potential ''herding'' effect of marine mammals into shallow waters, as was implicated in a mass stranding of melon headed whales off Madagascar during a multi-beam echosounder survey (Southall et al. 2013).

NMFS discussed these recommendations with Hilcorp to improve its monitoring and reporting measures, and to some extent, as well as mitigation measures. As a result, Hilcorp agrees to implement the following recommendations:

(1) Hilcorp will perform vessel-based marine mammal monitoring by protected species observers (PSOs) during vessel transit when the shallow geohazard survey is not being conducted. Marine mammal sighting data collected during the non-survey period will be compared with those during the survey to analyze the effects of the activities.

(2) Hilcorp and its contractor JASCO will deploy a high-frequency AMAR at the 5000 m site for detecting beluga clicks. The high-frequency AMAR would be operated at 380 kHz (16 bits) for about 2 minutes each hour and the rest of the time at 64 kHz (24 bits) for the 3 months deployment. The reason for deploying the high-frequency AMAR at 5000 m location, which NMFS concurs, is that there is a higher likelihood of detecting marine mammal acoustics in the deeper water farther from the island.

(3) Hilcorp will work with JASCO to use AMAR to collect data on cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers.

(4) Hilcorp will work with JASCO to ground-truth data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations and to include error rates for automatic detection to ensure the accurate classification of vocalizations by species.

(5) Hilcorp is open to sharing data and work with its contractor JASCO to collaborate with other researchers. In addition, Hilcorp and JASCO will make the passive acoustic recording data, including data on marine mammal vocalizations, publically available for researchers. These data sharing/collaboration efforts will enable scientists to purse a variety of studies concerning the acoustic environment, marine mammal bioacoustics, and potential activity effects on marine mammals in the survey area.

(6) Hilcorp will including information from high frequency acoustic recordings in reports to provide a better understanding of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and ⅓ octave bands.

Furthermore, Hilcorp agrees to implement the following mitigation recommendation and provided additional information in regard to the peer-review panel report:

(1) Hilcorp will specify that the delay for ramp-up and after a shut-down should be 15 minutes for species with short dive durations (small odontocetes and pinnipeds) and 30 minutes for species with longer diver durations (mysticetes and large odontocetes, including beluga whales).

(2) Regarding sound source information from the various active acoustic equipment proposed for Hilcorp's shallow geohazard survey, acoustic characteristics of these equipment or its equivalents were previously measured by JASCO. The measurement results in the following reports that are posted on NMFS Web site:

- Statoil 2011 Shallow Hazards Survey 90-day Report (Chapter 3) (*http://www.nmfs.noaa.gov/pr/pdfs/permits/statoil_90day_report2011.pdf*).
- Shell 2013 Shallow Hazards Survey 90-day Report (Chapter 2) (*http://www.nmfs.noaa.gov/pr/permits/incidental/oilgas/2013_shell_monitoringreport.pdf*).

(3) Regarding the panel's recommendation on Hilcorp's survey transect design, Hilcorp states that it can start in shallow water and work deeper to mitigate the potential ''herding'' effect. Hilcorp's plan is to divide the corridor into multiple sub-sections based on depth and work each section independently. This method is necessary for side scan sonar operations as each subsection will have a different range setting and line spacing that is related to depth.

All these aforementioned recommendations from the peer-review panel are included in the proposed mitigation and monitoring measures for Hilcorp's 2015 open-water shallow geohazard survey in the Beaufort Sea.

However, Hilcorp will not able to increase the number of vessel-based PSOs onboard the survey vessel. The number of PSOs onboard the vessel is limited by the available berth space. The survey vessels used for the proposed shallow geohazard survey can only accommodate maximum of 2 PSOs. Nevertheless, NMFS considers that due to the exceptionally small ensonified zones (no exclusion zone, with the radius of ZOI at 30 m from the source), one PSO on watch onboard the survey vessel is adequate.

In regard to an additional AMAR to be deployed in the vicinity of the survey area, NMFS worked with Hilcorp and determined that deployment of three AMARs would be cost prohibitive to Hilcorp, given the small project budget of the shallow geohazard survey. In addition, due to the short duration and minimal impact of the proposed shallow geohazard survey, the currently passive acoustic monitoring, improved with a high-frequency AMAR, is adequate to provide needed information to assess potential environmental effects from the proposed project.

Finally, NMFS does not agree with one of the panel's recommendations that Hilcorp limit operations at night or during periods of low visibility so that marine mammals do not enter the safety zone undetected. As mentioned previously, there is not no safety zone (exclusion zone) because of the low intensity high-frequency sonar

equipment being employed in the proposed shallow geohazard survey. In addition, limiting survey at night or during periods of low visibility would increase the survey duration, thus extend the noise output from survey vessels in the area. NMFS believes that as long as the 50-m ZOI is cleared of marine mammals before the ramp-up of sonar equipment during daylight hours with good visibility, shallow hazard survey can be carried out with minimum adverse effects to marine mammals.

*Reporting Measures*

(1) Technical Report

The results of Hilcorp's 2015 vessel-based monitoring, including estimates of ''take'' by harassment, will be presented in a ''90-day'' draft Technical Report, to be submitted to NMFS within 90 days after the end of the shallow geohazard survey, and then in a final Technical Report, which will address any comments NMFS had on the draft. The Technical Report will include:

(a) Summaries of monitoring effort (*e.g.*, total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(b) Analyses of the effects of various factors influencing detectability of marine mammals (*e.g.*, sea state, number of observers, and fog/glare);

(c) Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(d) Data analysis separated into periods when a sonar source is operating and when it is not, to better assess impacts to marine mammals—the final and comprehensive report to NMFS should summarize and plot:

- Data for periods when a sonar source is active and when it is not; and
- The respective predicted received sound conditions over fairly large areas (tens of km) around operations;

(e) Sighting rates of marine mammals during periods with and without sonar activities (and other variables that could affect detectability), such as:

- Initial sighting distances versus sonar activity state;
- Closest point of approach versus sonar activity state;
- Observed behaviors and types of movements versus sonar activity state;
- Numbers of sightings/individuals seen versus sonar activity state;
- Distribution around the survey vessel versus sonar activity state; and
- Estimates of take by harassment;

(f) Results from all hypothesis tests, including estimates of the associated statistical power, when practicable;

(g) Estimates of uncertainty in all take estimates, with uncertainty expressed by the presentation of confidence limits, a minimum-maximum, posterior probability distribution, or another applicable method, with the exact approach to be selected based on the sampling method and data available; and

(h) A clear comparison of authorized takes and the level of actual estimated takes.

In addition, the technical report will include analysis on acoustic monitoring such as:

(a) Cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers;

(b) Ground-truth of data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations with error rates for automatic detection to ensure the accurate classification of vocalizations by species; and

(c) Information of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and ⅓ octave bands.

Finally, Hilcorp will share data and work with its contractor JASCO to collaborate with other researchers. The passive acoustic recording data, including data on marine mammal vocalizations, will be made publically available for researchers. These data sharing/collaboration efforts will enable scientists to purse a variety of studies concerning the acoustic environment, marine mammal bioacoustics, and potential activity effects on marine mammals in the survey area.

(5) Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as a serious injury, or mortality (*e.g.*, ship-strike, gear interaction, and/or entanglement), Hilcorp would immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinators. The report would include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.*, wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Hilcorp to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Hilcorp would not be able to resume its activities until notified by NMFS via letter, email, or telephone.

In the event that Hilcorp discovers a dead marine mammal, and the lead PSO determines that the cause of the death is unknown and the death is relatively recent (*i.e.*, in less than a moderate state of decomposition as described in the next paragraph), Hilcorp would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Hilcorp to determine whether modifications in the activities are appropriate.

In the event that Hilcorp discovers a dead marine mammal, and the lead PSO determines that the death is not associated with or related to the activities authorized in the IHA (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Hilcorp would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators, within 24 hours of the discovery. Hilcorp would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Hilcorp

can continue its operations under such a case.

**Estimated Take by Incidental Harassment**

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed shallow geohazard survey. Noise propagation from subbottom profilers is expected to harass, through behavioral disturbance, affected marine mammal species or stocks.

The full suite of potential impacts to marine mammals from various industrial activities was described in detail in the ''Potential Effects of the Specified Activity on Marine Mammals'' section found earlier in this document. The potential effects of sound from the proposed shallow geohazard survey without any mitigation might include one or more of the following: Tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.*, 1995a). As discussed in the following sections in this document, NMFS estimates that Hilcorp's activities will most likely result in behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of one or more marine mammals. For reasons discussed previously in this document, hearing impairment (TTS and PTS) is highly unlikely to occur based on the fact that most of the equipment to be used during Hilcorp's proposed shallow geohazard survey does not have source levels high enough to elicit even mild TTS and/or the fact that certain species are expected to avoid the ensonified areas close to the operations. Additionally, non-auditory physiological effects are anticipated to be minor, if any would occur at all.

For impulsive sounds, such as the signals produced by the subbottom profiler sources during the shallow geohazard survey, NMFS uses a received level of 160-dB (rms) to indicate the onset of Level B harassment. Hilcorp provided calculations of the 160-dB isopleth produced by the subbottom profiler and then used that isopleth to estimate takes by harassment. Hilcorp provides a full description of the methodology used to estimate takes by harassment in its IHA application (see **ADDRESSES**), which is also provided in the following sections.

Hilcorp has requested authorization to take bowhead, gray, humpback, minke, killer, and beluga whales, harbor porpoise, and ringed, spotted, bearded, and ribbon seals incidental to shallow geohazard survey in the Beaufort Sea. However, as stated previously in this document, humpback, minke, and killer whales, harbor porpoise, and ribbon seal are considered extralimital in the proposed shallow geohazard survey area. Therefore, NMFS is not proposing to authorize take of these species.

*Basis for Estimating ''Take by Harassment''*

''Take by Harassment'' is described in this section and was calculated in Hilcorp's application by multiplying the expected densities of marine mammals that may occur near the shallow geohazard survey areas where received noise levels are higher than 160 dB re 1 μPa (rms) created by the subbottom profiler during the survey.

*Marine Mammal Density Estimates*

Whale species are migratory and therefore show a seasonal distribution, with different densities for the summer period (covering July and August) and the fall period (covering September and October). Seal species in the Beaufort Sea do not show a distinct seasonal distribution during the open water period between July and October. Data acquisition of the proposed sonar survey will only take place in summer (before start of Nuiqsut whaling), therefore only estimates of marine mammal densities for the summer are included in the take calculation. Whale and seal densities in the Beaufort Sea will further depend on the presence of sea ice. However, if ice cover within or close to the sonar survey area is more than approximately 10%, sonar survey activities may not start or be halted for safety reasons. Densities related to ice conditions are therefore not included in the take estimates.

Spatial differentiation is another important factor for marine mammal densities, both in latitudinal and longitudinal gradient. Taking into account the shallow water operations of the proposed sonar survey area and the associated area of influence, data from the nearshore zone of the Beaufort Sea is used for the calculation of densities, if available.

Density estimates are based on best available data. Because available data did not always cover the area of interest, estimates are subject to large temporal and spatial variation. Though correction factors for perception and availability bias have been calculated for certain coastal areas they were not always known for this study area. There is some uncertainty in the 2014 raw data and assumptions were used in the estimated number of exposures. To provide allowance for these uncertainties, maximum density estimates have been provided in addition to average density estimates.

A summary of marine mammal density in the proposed Hilcorp survey area is provided in Table 3.

TABLE 3—ESTIMATED SUMMER DENSITIES OF WHALES AND SIGHTING RATES OF SEALS (AVERAGE AND MAXIMUM) FOR THE PROPOSED NORTH PRUDHOE BAY SURVEY. DENSITIES ARE PROVIDED IN NUMBER OF INDIVIDUALS PER km$^2$ (IND/km$^2$), SIGHTING RATES IN NUMBER OF INDIVIDUALS PER HOUR (INDV/HR.).

| Species | Average | Maximum |
|---|---|---|
| | Summer Densities (INDV/km$^2$) | |
| Bowhead whale | 0.0088 | 0.0200 |
| Beluga | 0.0008 | 0.0078 |
| | Summer Sighting Rates (INDV/hr.) | |
| Ringed seal | 0.122 | 0.397 |
| Bearded seal | 0.033 | 0.107 |

TABLE 3—ESTIMATED SUMMER DENSITIES OF WHALES AND SIGHTING RATES OF SEALS (AVERAGE AND MAXIMUM) FOR THE PROPOSED NORTH PRUDHOE BAY SURVEY. DENSITIES ARE PROVIDED IN NUMBER OF INDIVIDUALS PER $km^2$ ($IND/km^2$), SIGHTING RATES IN NUMBER OF INDIVIDUALS PER HOUR (INDV/HR.).

| Species | Average | Maximum |
|---|---|---|
| Spotted seal | 0.039 | 0.126 |

*Level B Harassment Zone Distance*

As discussed earlier in this document, the operating frequencies of the multibeam, single-beam, and sidescan sonar equipment in Hilcorp's proposed shallow geohazard survey are above the hearing range of all marine mammals and therefore are not expected to have take of marine mammals. Estimated distance to sound pressure levels of 160 dB re 1 μPa, generated by the proposed sub-bottom equipment is 30 m from the source. However, as stated in this document earlier, Hilcorp proposes to implement a 50 m shutdown zone for the Level B behavioral harassment. Therefore, the calculation of marine mammal take is based on the number of animals exposed within the 50 m radius.

*Potential Number of ''Takes by Harassment''*

This section provides estimates of the number of individuals potentially exposed to pulsed sound levels ≥160 dB re 1 μPa rms by shallow geohazard survey using a subbottom profiler. The estimates are based on a consideration of the number of marine mammals that might be affected by operations in the Beaufort Sea during 2015 and the anticipated area exposed to those sound levels.

The potential number of bowhead whales and belugas that might be exposed to the 160 dB re 1 μPa (rms) sound pressure level was calculated by multiplying:

- The expected bowhead and beluga density as provided in Table 3;
- The total 160 dB re 1 μPa (rms) ensonified area in a single hour by the vessel travelling at 3 knots; and
- The estimated number of hours that the source vessels are operating.

The calculated area (0.0079 $km^2$) expected to be ensonified is determined based on the maximum distance to the 160 dB re 1 μPa (rms) sound pressure level for the Sub-bottom profiler, which is 0.05 km.

The estimated number of 24-hr days of sonar operations was determined by assuming a 25% downtime during the planned 45-day time span of the sonar survey period. Downtime is related to weather, equipment maintenance, mitigation implementation, and other circumstances. The total number of full 24-hr days that data acquisition is expected to occur is ~34 days or 816 hours.

The total 160 dB re 1 μPa (rms) ensonified area in a single hour by the vessel is calculated as 0.556 $km^2$/hr.

The average and maximum number of bowhead whales potentially exposed to sonar sound levels of 160 dB re 1μPa (rms) or more is estimated at 4 and 9 respectively. The limited number of exposures is due to the low estimated density of bowheads in Foggy Island Bay during July and August, the short duration of the survey, and the small acoustic footprint. For the requested authorization, the maximum number was increased by three to account for unexpected bowhead occurrences.

The average and maximum number of potential beluga exposures to 160 dB is <1. Belugas are known to show aggregate behavior and can occur in large numbers in nearshore zones, as evidenced by the sighting from Endicott in August 2013. Although beluga whales are not expected to frequent the vicinity of the Liberty Unit shallow geohazard survey area, their occurrence is still a possibility. To account for the potential average take of 1 beluga whale per day during the 45-day survey period, NMFS proposes a take authorization of 45 beluga whales for Hilcorp's shallow geohazard survey. Chance encounters with small numbers of other whale species are possible, but exposures to 160 dB or more are very unlikely for these species.

Although gray whale density is not known, this species has been occasionally sited in the Arctic, and Hilcorp is requesting takes of 3 individuals of gray whales by Level B behavioral harassment (Table 4).

The estimated number of seals that might be exposed to pulsed sounds of 160 dB re 1 μPa (rms) is calculated by multiplying:

- The expected species specific sighting rate as provided in Table 3; and
- The total number of hours that each source vessel will be operating during the data acquisition period.

The estimated number of hours that the sonar equipment will operate was determined by assuming a 25% downtime during a 45-day survey period, which is a total of 816 hours (34 days of 24 hour operations).

These estimated exposures do not take into account the mitigation measures that will be implemented, such as marine mammal observers watching for animals, shutdowns or power downs of the equipment when marine mammals are seen within defined ranges. These measures will further reduce the number of exposures and expected short-term reactions, and minimize any effects on hearing sensitivity.

A summary of the request takes and percent take among the population is provided in Table 4.

TABLE 4—THE TOTAL NUMBER OF POTENTIAL EXPOSURES OF MARINE MAMMALS TO SOUND LEVELS ≥160 dB re 1 μPa rms DURING THE HILCORP'S PROPOSED SHALLOW GEOHAZARD SURVEY IN THE BEAUFORT SEA, ALASKA, 2015. ESTIMATES ARE ALSO SHOWN AS A PERCENT OF EACH POPULATION

| Species | Abundance | Number potential exposure | % Estimated population |
|---|---|---|---|
| Beluga whale (Beaufort Sea stock) | 39,258 | 45 | 0.11 |
| Bowhead whale | 19,534 | 12 | 0.06 |
| Gray whale | 19,126 | 3 | 0.02 |
| Bearded seal | 155,000 | 100 | 0.06 |
| Ringed seal | 300,000 | 350 | 0.17 |

TABLE 4—THE TOTAL NUMBER OF POTENTIAL EXPOSURES OF MARINE MAMMALS TO SOUND LEVELS ≥160 dB re 1 μPa rms DURING THE HILCORP'S PROPOSED SHALLOW GEOHAZARD SURVEY IN THE BEAUFORT SEA, ALASKA, 2015. ESTIMATES ARE ALSO SHOWN AS A PERCENT OF EACH POPULATION—Continued

| Species | Abundance | Number potential exposure | % Estimated population |
|---|---|---|---|
| Spotted seal | 141,479 | 120 | 0.08 |

**Analysis and Preliminary Determinations**

*Negligible Impact*

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

No injuries or mortalities are anticipated to occur as a result of Hilcorp's proposed shallow geohazard survey, and none are proposed to be authorized. Additionally, animals in the area are not expected to incur hearing impairment (*i.e.*, TTS or PTS) or non-auditory physiological effects. The takes that are anticipated and authorized are expected to be limited to short-term Level B behavioral harassment. While the sonar sources are expected to be operated for approximately 45 days, the project timeframe will occur when cetacean species are typically not found in the project area or are found only in low numbers. While pinnipeds are likely to be found in the proposed project area more frequently, their distribution is dispersed enough that they likely will not be in the Level B harassment zone continuously. As mentioned previously in this document, pinnipeds appear to be more tolerant of anthropogenic sound than mysticetes.

Most of the marine mammals encountered will likely show overt disturbance (avoidance) only if they receive sonar sounds with levels ≥ 160 dB re 1 μPa. However, the estimated 160 dB zone is only 30 m from the source, which means that the animals have to be very close to the source vessel to be exposure to noise levels that could cause Level B harassment. In addition, Hilcorp will implement shutdown measures if a marine mammal is sighted within or is moving towards the 160 dB isopleths.

Taking into account the mitigation measures that are planned, effects on marine mammals are generally expected to be restricted to avoidance of a limited area around Hilcorp's proposed open-water activities and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment.'' Mitigation measures, such as controlled vessel speed, dedicated marine mammal observers, non-pursuit, ramp up procedures, and shut downs or power downs when marine mammals are seen within or approaching the ZOI, will further reduce short-term reactions. In all cases, the effects are expected to be short-term, with no lasting biological consequence.

Of the six marine mammal species likely to occur in the proposed marine survey area, bowhead whale and ringed seal are listed as endangered and threatened under the ESA, respectively. These species are also designated as ''depleted'' under the MMPA. Despite these designations, the Bering-Chukchi-Beaufort stock of bowheads has been increasing at a rate of 3.4 percent annually for nearly a decade (Allen and Angliss 2010). Additionally, during the 2001 census, 121 calves were counted, which was the highest yet recorded. The calf count provides corroborating evidence for a healthy and increasing population (Allen and Angliss 2010). There is no critical habitat designated in the U.S. Arctic for the bowhead whales. The Arctic stock of ringed seals have been listed by NMFS as threatened under the ESA. None of the other species that may occur in the project area are listed as threatened or endangered under the ESA or designated as depleted under the MMPA.

Potential impacts to marine mammal habitat were discussed previously in this document (see the ''Anticipated Effects on Habitat'' section). Although some disturbance of food sources of marine mammals is possible, any impacts are anticipated to be minor enough as to not affect rates of recruitment or survival of marine mammals in the area. The marine survey activities would occur in a localized area, and given the vast area of the Arctic Ocean where feeding by marine mammals occurs, any missed feeding opportunities in the direct project area could be offset by feeding opportunities in other available feeding areas.

In addition, no important feeding or reproductive areas are known in the vicinity of Hilcorp's proposed shallow geohazard survey. No critical habitat of ESA-listed marine mammal species occurs in the Beaufort Sea.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from Hilcorp's proposed shallow geohazard survey in the Beaufort Sea, Alaska, will have a negligible impact on the affected marine mammal species or stocks.

*Small Numbers*

The requested takes proposed to be authorized represent less than 0.2% of all populations or stocks potentially impacted (see Table 4 in this document). These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment if each animal is taken only once. The numbers of marine mammals estimated to be taken are small proportions of the total populations of the affected species or stocks. In addition, the mitigation and monitoring measures (described previously in this document) proposed for inclusion in the IHA (if issued) are expected to reduce even further any potential disturbance to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

**Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses**

*Relevant Subsistence Uses*

Marine mammals are legally hunted in Alaskan waters by coastal Alaska Natives and represent between 60% and 80% of their total subsistence harvest. The species regularly harvested by subsistence hunters in and around the Beaufort Sea are bowhead and beluga whales, and ringed, spotted, and bearded seals. The importance of each of the subsistence species varies among the communities and is mainly based on availability and season.

The communities closest to the project area are, from west to east, the villages of Barrow, Nuiqsut and Kaktovik. Barrow is located >200 mi west from the Hilcorp's proposed survey area. It is the largest community on the Alaska's Beaufort Sea coast. Important marine subsistence resources for Barrow include bowhead and beluga whales, and ice seals. Nuiqsut is located near the mouth of the Colville River, about 55 mi southwest of the proposed project area. Most important marine subsistence resource for Nuiqsut is the bowhead whale, and to a lesser extent belugas and seals. Nuiqsut hunters use Cross Island, (~20 mi northwest of the project area) as a base to hunt for bowhead whales during the fall migration and have historically hunted bowhead whales as far east as Flaxman Island. Kaktovik is located on Barter Island, about 120 mi east of the project area. Major marine subsistence resources include bowhead and beluga whales, and seals.

(1) Bowhead Whale

The bowhead whale is a critical subsistence and cultural resource for the North Slope communities of Barrow, Nuiqsut, and Kaktovik. The level of allowable harvest is determined under a quota system in compliance with the International Whaling Commission (IWC 1980; Gambell 1982). The quota is based on the nutritional and cultural needs of Alaskan Natives as well as on estimates of the size and growth of the Bering-Chukchi-Beaufort seas stock of bowhead whales (Donovan 1982; Braund 1992). The AEWC allots the number of bowhead whales that each community is permitted to harvest. Contemporary whaling in Kaktovik dates from 1964 and in Nuiqsut from 1973 (EDAW/AECOM 2007; Galginaitis and Koski 2002). The number of boats used or owned in 2011 by the subsistence whaling crew of the villages of Kaktovik, Nuiqsut, and Barrow was 8, 12, and 40, respectively. These numbers presumably change from year to year.

Bowhead harvesting in Barrow occurs both during the spring (April–May) and fall (September–October) when the whales migrate relatively close to shore (ADNR 2009). During spring bowheads migrate through open ice leads close to shore. The hunt takes place from the ice using umiaks (bearded seal skin boats). During the fall, whaling is shore-based and boats may travel up to 30 mi a day (EDAW/AECOM 2007). In Barrow, most whales were historically taken during spring whaling. More recently, however, the efficiency of the spring harvest appeared to be lower than the autumn harvest due to ice and weather conditions as well as struck whales escaping under the ice (Suydam *et al.* 2010). In the past few years the bowhead fall hunt has become increasingly important.

Nuiqsut and Kaktovik hunters harvest bowhead whales only during the fall. The bowhead spring migration in the Beaufort Sea occurs too far from shore for hunting because ice leads do not open up nearshore (ADNR 2009). In Nuiqsut, whaling takes place from early September through mid-to-late September as the whales migrate west (EDAW/AECOM 2007). Three to five whaling crews base themselves at Cross Island, a barrier island approximately 20 mi northwest of the Liberty Unit shallow geohazard survey area. Nuiqsut whalers harvest an average of 2 bowheads each year. Whaling from Kaktovik also occurs in the fall, primarily from late August through late September or early October (EDAW/AECOM 2007). Kaktovik whalers hunt from the Okpilak and Hulahula rivers east to Tapkaurak Point (ADNR 2009). Whaling activities are staged from the community rather than remote camps; most whaling takes place within 12 mi of the community (ADNR 2009). Kaktovik whalers harvest an average of 2–3 bowhead whales each year.

(2) Beluga

The harvest of belugas is managed cooperatively through an agreement between NMFS and the Alaska Beluga Whale Committee (ABWC). From 2005–2009, between 5 and 48 belugas were harvested annually from the Beaufort Sea stock (Allen and Angliss 2014); with a mean annual take of 25.8 animals. Both Nuiqsut and Kaktovik harvest few belugas, mostly opportunistically during the fall bowhead hunt.

(3) Seals

Seals represent an important subsistence resource for the North Slope communities. Harvest of bearded seals usually takes place during the spring and summer open water season from Barrow (EDAW/AECOM 2007) with only a few animals taken by hunters from Kaktovik or Nuiqsut. Seals are also taken during the ice-covered season, with peak hunting occurring in February (ADNR 2009). In 2003, Barrow-based hunters harvested 776 bearded seals, 413 ringed seals and 12 spotted seals (ADNR 2009). Nuiqsut hunters harvest seals in an area from Cape Halkett to Foggy Island Bay. For the period 2000–2001, Nuiqsut hunters harvested one bearded seal and 25 ringed seals (ADNR 2009). Kaktovik hunters also hunt seals year-round. In 2002–2003, hunters harvested 8 bearded seals and 17 ringed seals.

*Potential Impacts to Subsistence Uses*

NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as: ''an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The proposed shallow geohazard survey will take place between July 1 and September 30, 2015, with data acquisition occurring in July and August. The project area is located >200 mi east from Barrow, approximately 55 mi northeast from Nuiqsut (20 mi southeast of Cross Island), and 120 mi west from Kaktovik. Potential impact on the subsistence hunt from the planned activities is expected mainly from sounds generated by sonar equipment. Due to the timing of the project and the distance from the surrounding communities, there will be no effects on spring harvesting and little or no effects on the occasional summer harvest of beluga and subsistence seal hunts (ringed and spotted seals are primarily harvested in winter while bearded seals are hunted during July-September in the Beaufort Sea). The community of

Nuiqsut may begin fall whaling activities in late August to early September from Cross Island (northwest of the survey area).

*Plan of Cooperation or Measures To Minimize Impacts to Subsistence Hunts*

(1) Plan of Cooperation

Regulations at 50 CFR 216.104(a)(12) require IHA applicants for activities that take place in Arctic waters to provide a Plan of Cooperation (POC) or information that identifies what measures have been taken and/or will be taken to minimize adverse effects on the availability of marine mammals for subsistence purposes.

Hilcorp has prepared a draft POC and is currently establishing a dialogue to coordinate activities with the villages. A POC will include the aforementioned mitigation measures and includes plans for and results of meetings with Alaska Native communities.

Liberty Unit was transferred to Hilcorp ownership along with the Northstar, Milne Point and Endicott facilities. Previously, BP Exploration, Alaska (BPXA) coordinated with communities and stakeholders regarding the Liberty Unit work during the 2014 season:

- December 13–14, 2012: Meeting with the Alaska Eskimo Whaling Commission (AEWC) and Whaling Captains' Associations during the AEWC Quarterly meeting in Anchorage.
- February 7–8, 2013: CAA discussions with AEWC and Whaling Captains' Associations during the AEWC Annual Convention in Barrow.

Hilcorp plans to continue attending the above meetings and has engaged stakeholders and Native community members throughout 2014. A list of meetings follows:

- Informal engagement with AEWC—July 2014
- Meeting with Native Village of Barrow leadership—August 2014
- Meeting with North Slope Borough (NSB) Wildlife Management Dept.—August 2014
- Meeting with NSB Assembly—August 2014
- Meeting with NSB Planning Commission—October 2014
- Presentation and discussion with AEWC—October 2014
- Meeting with NSB Jacob Adams and NSB Counsel—October 2014
- Cultural awareness/subsistence presentation and Q&A with Uum's Consulting—October 2014

Additional pre-season meetings maybe planned if needed to address additional requests for coordination. Any subsistence discussions will be documented and forwarded to the NMFS as part of the POC.

(2) Stakeholder Engagement

Hilcorp has begun discussions with the AEWC to develop a Conflict Avoidance Agreement (CAA) intended to minimize potential interference with bowhead subsistence hunting. Hilcorp will attend and participate in the CAA meetings scheduled in 2015. The CAA, when executed, will describe measures to minimize any adverse effects on the availability of bowhead whales for subsistence uses.

The North Slope Borough Department of Wildlife Management (NSB–DWM) was consulted, and the project was also presented to the NSB Planning Commission in January 2015. Hilcorp will hold meetings with key stakeholders in the community of Nuiqsut, Barrow, and Kaktovik to present the proposed project, address questions and concerns, and provide them with contact information of project management to which they can direct concerns during the survey.

The following are measures that Hilcorp will take to reduce impacts to the subsistence community:

- Hilcorp will comply with the CAA terms to address plans to meet with the affected community to resolve conflicts and notify the communities of any changes in the operation.
- Inupiat Marine Mammal Observers on board the vessels are tasked with looking out for whales and other marine mammals in the vicinity of the vessel to assist the vessel captain in avoiding harm to whales and other marine mammals.
- Vessels will be operated in a manner to avoid areas where species that are sensitive to noise or movement are concentrated at times when such species are concentrated.
- Communications and conflict resolution are detailed in the CAA. Hilcorp is planning to participate in the Communications Center that is operated annually during the bowhead subsistence hunt.
- Communications with the villages of Barrow, Kaktovik, and Nuiqsut—discuss community questions or concerns including all subsistence hunting activities.

(3) Future Plan of Cooperation Consultations

Hilcorp plans to engage with the relevant subsistence communities regarding its future Beaufort Sea activities. With regard to the 2015 Liberty Unit shallow geohazard survey project, Hilcorp will present the data on marine mammal sightings and the results of the marine mammal monitoring and mitigation as part of our 90-day report to the regulatory authorities.

*Unmitigable Adverse Impact Analysis and Preliminary Determination*

NMFS considers that these mitigation measures including measures to reduce overall impacts to marine mammals in the vicinity of the proposed shallow geohazard survey area and measures to mitigate any potential adverse effects on subsistence use of marine mammals are adequate to ensure subsistence use of marine mammals in the vicinity of Hilcorp's proposed survey in the Beaufort Sea.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from Hilcorp's proposed activities.

**Endangered Species Act (ESA)**

There are two marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the proposed project area: The bowhead whale and ringed seal. NMFS' Permits and Conservation Division has initiated consultation with NMFS' Endangered Species Division under section 7 of the ESA on the issuance of an IHA to Hilcorp under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

**National Environmental Policy Act (NEPA)**

NMFS is preparing an Environmental Assessment (EA), pursuant to NEPA, to determine whether the issuance of an IHA to Hilcorp for its 2015 shallow geohazard activities may have a significant impact on the human environment. NMFS has released a draft of the EA for public comment along with this proposed IHA.

**Proposed Authorization**

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Hilcorp for conducting shallow geohazard survey in the Beaufort Sea during the 2015 Arctic open-water season, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed IHA language is provided next.

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

(1) This Authorization is valid from July 1, 2015, through September 30, 2015.

(2) This Authorization is valid only for activities associated with Hilcorp's 2015 Beaufort Sea shallow geohazard survey. The specific area where Hilcorp's shallow geohazard survey will be conducted lies within Foggy Island Bay in the U.S. Beaufort Sea, as shown in Figure 1 of Hilcorp's IHA application.

(3)(a) The incidental taking of marine mammals, by Level B harassment only, is limited to the following species: Bowhead whale; gray whale; beluga whale; ringed seal; bearded seal; and spotted seal, as shown in Table 4.

(3)(b) The authorization for taking by harassment is limited to the following acoustic sources and from the following activities:

(i) Sonar sources used for shallow geohazard survey; and

(ii) Vessel activities related to the shallow geohazard survey.

(3)(c) The taking of any marine mammal in a manner prohibited under this Authorization must be reported within 24 hours of the taking to the Alaska Regional Administrator (907–586–7221) or his designee in Anchorage (907–271–3023), National Marine Fisheries Service (NMFS) and the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at (301) 427–8401, or her designee (301–427–8418).

(4) The holder of this Authorization must notify the Chief of the Permits and Conservation Division, Office of Protected Resources, at least 48 hours prior to the start of shallow geohazard survey (unless constrained by the date of issuance of this Authorization in which case notification shall be made as soon as possible).

(5) Prohibitions

(a) The taking, by incidental harassment only, is limited to the species listed under condition 3(a) above and by the numbers listed in Table 4. The taking by injury or death of these species or the taking by harassment, injury or death of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this Authorization.

(b) The taking of any marine mammal is prohibited whenever the required source vessel protected species observers (PSOs), required by condition 7(a)(i), are not onboard in conformance with condition 7(a)(i) of this Authorization.

(6) Mitigation

(a) Establishing Zone of Influence (ZOI)

(i) Establish and monitor with trained PSOs a ZOI zone surrounding the sub-bottom profiler on the source vessel where the received level would be 160 dB (rms) re 1 μPa for all marine mammals.

(ii) The sizes of the ZOI is 50 m radius from the source vessel.

(b) Vessel Movement Mitigation:

(i) Avoid concentrations or groups of whales by all vessels under the direction of Hilcorp.

(ii) If any vessel approaches within 1.6 km (1 mi) of observed bowhead whales, except when providing emergency assistance to whalers or in other emergency situations, the vessel operator will take reasonable precautions to avoid potential interaction with the bowhead whales by taking one or more of the following actions, as appropriate:

(A) Reducing vessel speed to less than 5 knots within 300 yards (900 feet or 274 m) of the whale(s);

(B) Steering around the whale(s) if possible;

(C) Operating the vessel(s) in such a way as to avoid separating members of a group of whales from other members of the group;

(D) Operating the vessel(s) to avoid causing a whale to make multiple changes in direction; and

(E) Checking the waters immediately adjacent to the vessel(s) to ensure that no whales will be injured when the propellers are engaged.

(iii) When weather conditions require, such as when visibility drops, adjust vessel speed accordingly, but not to exceed 5 knots, to avoid the likelihood of injury to whales.

(iv) In general, the survey design will start in shallow water and work deeper to mitigate the potential ''herding'' effect.

(c) Mitigation Measures for Sonar Sources

(i) Ramp-up:

(A) A ramp up, following a cold start, can be applied if the ZOI has been free of marine mammals for a consecutive 30-minute period. The entire ZOI must have been visible during these 30 minutes. If the entire ZOI is not visible, then ramp up from a cold start cannot begin.

(B) If a marine mammal(s) is sighted within the ZOI during the 30-minute watch prior to ramp up, ramp up will be delayed until the marine mammal(s) is sighted outside of the ZOI or the animal(s) is not sighted for at least 15 minutes for pinnipeds, or 30 minutes for cetaceans.

(C) If, for any reason, the sub-bottom profiler has been discontinued for a period of 10 minutes or more, ramp-up procedures shall be implemented. If the PSO watch has been suspended during that time, a 30-minute clearance of the ZOI is required prior to commencing ramp-up. Discontinuation of sonar activity for less than 10 minutes does not require a ramp-up.

(D) The survey operator and PSOs shall maintain records of the times when ramp-ups start and when the sub-bottom profiler reaches full power.

(ii) Power-down/Shutdown:

(A) The sub-bottom profiler shall be immediately powered down whenever a marine mammal is sighted approaching close to or within the sub-bottom profiler at full power, but is outside the ZOI of the sub-bottom profiler at reduced power.

(B) If a marine mammal is already within or is about to enter the ZOI when first detected, the sub-bottom profiler shall be shutdown immediately.

(C) After showdown for more than 10 minutes, ramp-up shall not start until after the marine mammal is visually seen left the ZOI; or 15 minutes have passed after the last detection of the marine mammal with shorter dive durations (pinnipeds and small odontocetes); or 30 minutes have passed after the last detection of the marine mammal with longer diver durations (mysticetes and large odontocetes, including beluga whales).

(iii) Poor Visibility Conditions:

(A) If during foggy conditions, heavy snow or rain, or darkness, the full 160 dB ZOI is not visible, the sub-bottom profiler cannot commence a ramp-up procedure from a full shut-down.

(B) If the sub-bottom profiler has been operational before nightfall or before the onset of poor visibility conditions, they can remain operational throughout the night or poor visibility conditions.

(iv) Firing Sub-bottom Profiler During Turns and Transits

(A) Throughout the shallow geohazard survey, during turning movements and short transits, Hilcorp will employ the use of the lowest setting for the sub-bottom profiler to deter marine mammals from being within the immediate area of the survey. The sub-bottom profiler would be operated at approximately one shot per minute and would not be operated for longer than three hours in duration.

(d) Mitigation Measures for Subsistence Activities:

(i) For the purposes of reducing or eliminating conflicts between

subsistence whaling activities and Hilcorp's survey program, the holder of this Authorization will participate with other operators in the Communication and Call Centers (Com-Center) Program. Com-Centers will be operated to facilitate communication of information between Hilcorp and subsistence whalers. The Com-Centers will be operated 24 hours/day during the 2015 fall subsistence bowhead whale hunt.

(ii) All vessels shall report to the appropriate Com-Center at least once every six hours, commencing each day with a call at approximately 06:00 hours.

(iii) The appropriate Com-Center shall be notified if there is any significant change in plans. The appropriate Com-Center also shall be called regarding any unsafe or unanticipated ice conditions.

(iv) Upon notification by a Com-Center operator of an at-sea emergency, the holder of this Authorization shall provide such assistance as necessary to prevent the loss of life, if conditions allow the holder of this Authorization to safely do so.

(v) Hilcorp shall monitor the positions of all of its vessels and exercise due care in avoiding any areas where subsistence activity is active.

(vi) Routing barge and transit vessels:

(A) Vessels transiting in the Beaufort Sea east of Bullen Point to the Canadian border shall remain at least 5 miles offshore during transit along the coast, provided ice and sea conditions allow.

(B) From August 31 to October 31, vessels in the Chukchi Sea or Beaufort Sea shall remain at least 20 miles offshore of the coast of Alaska from Icy Cape in the Chukchi Sea to Pitt Point on the east side of Smith Bay in the Beaufort Sea, unless ice conditions or an emergency that threatens the safety of the vessel or crew prevents compliance with this requirement. This condition shall not apply to vessels actively engaged in transit to or from a coastal community to conduct crew changes or logistical support operations.

(C) Vessels shall be operated at speeds necessary to ensure no physical contact with whales occurs, and to make any other potential conflicts with bowheads or whalers unlikely. Vessel speeds shall be less than 10 knots in the proximity of feeding whales or whale aggregations.

(D) If any vessel inadvertently approaches within 1.6 kilometers (1 mile) of observed bowhead whales, except when providing emergency assistance to whalers or in other emergency situations, the vessel operator will take reasonable precautions to avoid potential interaction with the bowhead whales by taking one or more of the following actions, as appropriate:

- Reducing vessel speed to less than 5 knots within 900 feet of the whale(s);
- Steering around the whale(s) if possible;
- Operating the vessel(s) in such a way as to avoid separating members of a group of whales from other members of the group;
- Operating the vessel(s) to avoid causing a whale to make multiple changes in direction; and
- Checking the waters immediately adjacent to the vessel(s) to ensure that no whales will be injured when the propellers are engaged.

(vii) Hilcorp shall complete operations in time to allow such vessels to complete transit through the Bering Strait to a point south of 59 degrees North latitude no later than November 15, 2015. Any vessel that encounters weather or ice that will prevent compliance with this date shall coordinate its transit through the Bering Strait to a point south of 59 degrees North latitude with the appropriate Com-Centers. Hilcorp vessels shall, weather and ice permitting, transit east of St. Lawrence Island and no closer than 10 miles from the shore of St. Lawrence Island.

(7) Monitoring

(a) Vessel-based Visual Monitoring:

(i) Vessel-based visual monitoring for marine mammals shall be conducted by NMFS-approved PSOs throughout the period of survey activities.

(ii) PSOs shall be stationed aboard the survey vessels through the duration of the surveys.

(iii) A sufficient number of PSOs shall be onboard the survey vessel to meet the following criteria:

(A) 100% monitoring coverage during all periods of survey operations in daylight;

(B) Maximum of 4 consecutive hours on watch per PSO; and

(C) Maximum of 12 hours of watch time per day per PSO.

(iv) The vessel-based marine mammal monitoring shall provide the basis for real-time mitigation measures as described in (6)(c) above.

(v) Results of the vessel-based marine mammal monitoring shall be used to calculate the estimation of the number of ''takes'' from the marine surveys and equipment recovery and maintenance program.

(b) Protected Species Observers and Training

(i) PSO teams shall consist of Inupiat observers and NMFS-approved field biologists.

(ii) Experienced field crew leaders shall supervise the PSO teams in the field. New PSOs shall be paired with experienced observers to avoid situations where lack of experience impairs the quality of observations.

(iii) Crew leaders and most other biologists serving as observers in 2015 shall be individuals with experience as observers during recent seismic or shallow hazards monitoring projects in Alaska, the Canadian Beaufort, or other offshore areas in recent years.

(iv) Resumes for PSO candidates shall be provided to NMFS for review and acceptance of their qualifications. Inupiat observers shall be experienced in the region and familiar with the marine mammals of the area.

(v) All observers shall complete a training course designed to familiarize individuals with monitoring and data collection procedures. The training course shall be completed before the anticipated start of the 2015 open-water season. The training session(s) shall be conducted by qualified marine mammalogists with extensive crew-leader experience during previous vessel-based monitoring programs.

(vi) Crew members should not be used as primary PSOs because they have other duties and generally do not have the same level of expertise, experience, or training as PSOs, but they could be stationed on the fantail of the vessel to observe the near field, especially the area around the survey vessels, and implement a power-down or shutdown if a marine mammal enters the safety zone (or exclusion zone).

(vii) If crew members are to be used as PSOs, they shall go through some basic training consistent with the functions they will be asked to perform. The best approach would be for crew members and PSOs to go through the same training together.

(viii) PSOs shall be trained using visual aids (*e.g.,* videos, photos), to help them identify the species that they are likely to encounter in the conditions under which the animals will likely be seen.

(ix) Hilcorp shall train its PSOs to follow a scanning schedule that consistently distributes scanning effort according to the purpose and need for observations. All PSOs should follow the same schedule to ensure consistency in their scanning efforts.

(x) PSOs shall be trained in documenting the behaviors of marine mammals. PSOs should record the primary behavioral state (*i.e.,* traveling, socializing, feeding, resting, approaching or moving away from vessels) and relative location of the observed marine mammals.

(c) Marine Mammal Observation Protocol

(i) PSOs shall watch for marine mammals from the best available vantage point on the survey vessels, typically the bridge.

(ii) Observations by the PSOs on marine mammal presence and activity shall begin a minimum of 30 minutes prior to the estimated time that the sub-bottom profiler is to be turned on and/or ramped-up. Monitoring shall continue during the survey operations and last until 30 minutes after the sonar equipment stop firing.

(iii) For comparison purposes, PSOs shall also document marine mammal occurrence, density, and behavior during at least some periods when the sonar equipment used for survey is off.

(iv) PSOs will scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7 × 50 and 16–40 × 80) and with the naked eye. GPS unit and laptop computer(s) will also be available for PSOs onboard survey vessels.

(v) Personnel on the bridge shall assist the marine mammal observer(s) in watching for marine mammals.

(vi) PSOs aboard the marine survey vessel shall give particular attention to the areas within the marine mammal ZOI around the source vessel, as noted in (6)(a)(i) and (ii). They shall avoid the tendency to spend too much time evaluating animal behavior or entering data on forms, both of which detract from their primary purpose of monitoring the exclusion zone.

(vii) Monitoring shall consist of recording of the following information:

(A) The species, group size, age/size/sex categories (if determinable), the general behavioral activity, heading (if consistent), bearing and distance from survey vessel, sighting cue, behavioral pace, and apparent reaction of all marine mammals seen near the survey vessel (*e.g.,* none, avoidance, approach, paralleling, etc);

(B) The time, location, heading, speed, and activity of the vessel (sub-bottom profiler firing or not), along with sea state, visibility, cloud cover and sun glare at (I) any time a marine mammal is sighted (including pinnipeds hauled out on barrier islands), (II) at the start and end of each watch, and (III) during a watch (whenever there is a change in one or more variable);

(C) The identification of all vessels that are visible within 5 km of the survey vessel whenever a marine mammal is sighted and the time observed;

(D) Any identifiable marine mammal behavioral response (sighting data should be collected in a manner that will not detract from the PSO's ability to detect marine mammals);

(E) Any adjustments made to operating procedures; and

(F) Visibility during observation periods so that total estimates of take can be corrected accordingly.

(vii) Distances to nearby marine mammals will be estimated with binoculars containing a reticle to measure the vertical angle of the line of sight to the animal relative to the horizon. Observers may use a laser rangefinder to test and improve their abilities for visually estimating distances to objects in the water.

(viii) PSOs shall understand the importance of classifying marine mammals as ''unknown'' or ''unidentified'' if they cannot identify the animals to species with confidence. In those cases, they shall note any information that might aid in the identification of the marine mammal sighted. For example, for an unidentified mysticete whale, the observers should record whether the animal had a dorsal fin.

(ix) Additional details about unidentified marine mammal sightings, such as ''blow only,'' mysticete with (or without) a dorsal fin, ''seal splash,'' etc., shall be recorded.

(x) When a marine mammal is seen approaching or within the exclusion zone applicable to that species, the marine survey crew shall be notified immediately so that mitigation measures described in (6) can be promptly implemented.

(d) Field Data-Recording and Verification

(i) PSOs aboard the vessels shall maintain a digital log of shallow geohazard survey, noting the date and time of all changes in survey activity (ramp-up, power-down, shutdowns, etc.) and any corresponding changes in monitoring radii in a software spreadsheet.

(ii) PSOs shall utilize a standardized format to record all marine mammal observations and mitigation actions (sub-bottom profiler power-downs, shut-downs, and ramp-ups).

(iii) Information collected during marine mammal observations shall include the following:

(A) Vessel speed, position, and activity
(B) Date, time, and location of each marine mammal sighting
(C) Number of marine mammals observed, and group size, sex, and age categories
(D) Observer's name and contact information
(E) Weather, visibility, and ice conditions at the time of observation
(F) Estimated distance of marine mammals at closest approach
(G) Activity at the time of observation, including possible attractants present
(H) Animal behavior
(I) Description of the encounter
(J) Duration of encounter
(K) Mitigation action taken

(iv) Data shall be recorded directly into handheld computers or as a back-up, transferred from hard-copy data sheets into an electronic database.

(v) A system for quality control and verification of data shall be facilitated by the pre-season training, supervision by the lead PSOs, and in-season data checks, and shall be built into the software.

(vi) Computerized data validity checks shall also be conducted, and the data shall be managed in such a way that it is easily summarized during and after the field program and transferred into statistical, graphical, or other programs for further processing.

(e) Passive Acoustic Monitoring

(i) Hilcorp shall conduct passive acoustic monitoring using fixed hydrophone(s) to

(A) Document ambient noise conditions;

(B) Examine the spatial and temporal distribution of marine mammals based on acoustic detections of their vocalizations; and

(C) Characterize the long-range propagation of sounds produced during the geohazard survey; and

(ii) Bottom-Mounted Acoustic Sensors:

(A) Recorders shall be capable of recording marine mammal sounds and making both ambient and anthropogenic noise measurements.

(B) Two recorders be deployed near the Liberty prospect and be aligned with the geohazard survey line, at distances of 500 m (AMAR with sampling rate of 64 kHz) and 5000 m (AMAR with sampling rate of 380 kHz) from the offshore end of the survey line.

(C) Recorders shall be located inside of the barrier islands.

(8) Data Analysis and Presentation in Reports

(a) Estimation of potential takes or exposures shall be improved for times with low visibility (such as during fog or darkness) through interpolation or possibly using a probability approach. Those data could be used to interpolate possible takes during periods of restricted visibility.

(b) Hilcorp shall provide the information collected, plus a number of summary analyses and graphics to help NMFS assess the potential impacts of

Hilcorp's survey. Specific summaries/analyses/graphics would include:

(i) A table or other summary of survey activities (*i.e.,* did the survey proceed as planned);

(ii) A table of sightings by time, location, species, and distance from the survey vessel;

(iii) A geographic depiction of sightings for each species by area and month;

(iv) A table and/or graphic summarizing behaviors observed by species;

(v) A table and/or graphic summarizing observed responses to the survey by species;

(vi) A table of mitigation measures (*e.g.,* power-downs, shutdowns) taken by date, location, and species;

(vii) A graphic of sightings by distance for each species and location;

(viii) A table or graphic illustrating sightings during the survey versus sightings when the sub-bottom profiler was silent; and

(ix) A summary of times when the survey was interrupted because of interactions with marine mammals.

(c) Hilcorp shall collaborate with other industrial operators in the area to integrate and synthesize monitoring results as much as possible (such as submitting ''sightings'' from their monitoring projects to an online data archive, such as OBIS–SEAMAP) and archive and make the complete databases available upon request.

(9) Reporting

(a) Technical report: A draft technical report will be submitted to the Director, Office of Protected Resources, NMFS, within 90 days after the end of HIlcorp's 2015 open-water shallow geohazard survey in the Beaufort Sea. The report will describe in detail:

(i) Summaries of monitoring effort (*e.g.,* total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(ii) Summaries that represent an initial level of interpretation of the efficacy, measurements, and observations, rather than raw data, fully processed analyses, or a summary of operations and important observations;

(iii) Summaries of all mitigation measures (*e.g.,* operational shutdowns if they occur) and an assessment of the efficacy of the monitoring methods;

(iv) Analyses of the effects of various factors influencing detectability of marine mammals (*e.g.,* sea state, number of observers, and fog/glare);

(v) Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(vi) Data analysis separated into periods when the sub-bottom profiler is operating and when it is not, to better assess impacts to marine mammals;

(vii) Sighting rates of marine mammals during periods with and without the sub-bottom profiler (and other variables that could affect detectability), such as:

(A) Initial sighting distances versus survey activity state;

(B) Closest point of approach versus survey activity state;

(C) Observed behaviors and types of movements versus survey activity state;

(D) Numbers of sightings/individuals seen versus survey activity state;

(E) Distribution around the survey vessel versus survey activity state; and

(F) Estimates of take by harassment;

(viii) A clear comparison of authorized takes and the level of actual estimated takes;

(ix) Cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers;

(x) Ground-truth of data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations with error rates for automatic detection to ensure the accurate classification of vocalizations by species; and

(xi) Information of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and ⅓ octave bands.

(b) The draft technical report shall be subject to review and comment by NMFS. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS. The draft report will be considered the final report for this activity under this Authorization if NMFS has not provided comments and recommendations within 90 days of receipt of the draft report.

(c) Hilcorp will share data and work with its contractor JASCO to collaborate with other researchers. The passive acoustic recording data, including data on marine mammal vocalizations, will be made publically available for researchers.

(10)(a) In the unanticipated event that survey operations clearly cause the take of a marine mammal in a manner prohibited by this Authorization, such as an injury or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), Hilcorp shall immediately cease survey operations and immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barbara.Mahoney@noaa.gov*). The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the incident;

(ii) The name and type of vessel involved;

(iii) The vessel's speed during and leading up to the incident;

(iv) Description of the incident;

(v) Status of all sound source use in the 24 hours preceding the incident;

(vi) Water depth;

(vii) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

(viii) Description of marine mammal observations in the 24 hours preceding the incident;

(ix) Species identification or description of the animal(s) involved;

(x) The fate of the animal(s); and

(xi) Photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with Hilcorp to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Hilcorp may not resume their activities until notified by NMFS via letter, email, or telephone.

(b) In the event that Hilcorp discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), Hilcorp will immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the NMFS Alaska Stranding Hotline (1–877–925–7773) and/or by email to the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barabara.Mahoney@noaa.gov*). The report must include the same information identified in Condition 10(a) above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Hilcorp to determine whether

modifications in the activities are appropriate.

(c) In the event that Hilcorp discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in Condition 3 of this Authorization (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Hilcorp shall report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the NMFS Alaska Stranding Hotline (1–877–925–7773) and/or by email to the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barbara.Mahoney@noaa.gov*), within 24 hours of the discovery. Hilcorp shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Hilcorp can continue its operations under such a case.

(11) Activities related to the monitoring described in this Authorization do not require a separate scientific research permit issued under section 104 of the Marine Mammal Protection Act.

(12) The Plan of Cooperation outlining the steps that will be taken to cooperate and communicate with the native communities to ensure the availability of marine mammals for subsistence uses, must be implemented.

(13) This Authorization may be modified, suspended, or withdrawn if the holder fails to abide by the conditions prescribed herein or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals, or if there is an unmitigable adverse impact on the availability of such species or stocks for subsistence uses.

(14) A copy of this Authorization and the Incidental Take Statement must be in the possession of each survey vessel operator taking marine mammals under the authority of this Incidental Harassment Authorization.

(15) Hilcorp is required to comply with the Terms and Conditions of the Incidental Take Statement corresponding to NMFS' Biological Opinion.

## Request for Public Comments

NMFS requests comment on our analysis, the draft authorization, and any other aspect of the Notice of Proposed IHA for Hilcorp's proposed shallow geohazard survey in the Beaufort Sea. Please include with your comments any supporting data or literature citations to help inform our final decision on Hilcorp's request for an MMPA authorization.

Dated: May 11, 2015.

**Donna S. Wieting,**

*Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–11701 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–22–P

---

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XU02**

### Endangered and Threatened Species; Draft Recovery Plan for the Cook Inlet Beluga Whale

**AGENCY:** National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The National Marine Fisheries Service (NMFS) announces the availability of the Cook Inlet Beluga Whale (*Delphinapterus leucas*) Draft Recovery Plan for public review. NMFS is soliciting review and comment from the public and all interested parties on the draft Plan, and will consider all substantive comments received during the review period before submitting the Plan for final approval.

**DATES:** Comments on the draft Plan must be received by close of business on July 14, 2015.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NMFS–2015–0053 by either of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0053,*

2. Click the ''Comment Now!'' icon and complete the required fields,

3. Enter or attach your comments.

• *Mail:* Submit written comments to Jon Kurland, Assistant Regional Administrator for Protected Resources, National Marine Fisheries Service, Alaska Regional Office, Protected Resources Division, P.O. Box 21668, 709 W. 9th St., Rm. 420, Juneau, Alaska 99802–1668.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive or protected information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

**FOR FURTHER INFORMATION CONTACT:** Mandy Migura (907–271–1332), email *Mandy.Migura@noaa.gov* or Therese Conant (301–427–8456), email *Therese.Conant@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

## Background

Recovery plans describe actions beneficial to the conservation and recovery of species listed under the Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*). Section 4(f)(1) of the ESA requires that recovery plans incorporate: (1) Objective, measurable criteria which, when met, would result in a determination that the species is no longer threatened or endangered; (2) site-specific management actions necessary to achieve the Plan's goals; and (3) estimates of the time required and costs to implement recovery actions. The ESA requires the development of recovery plans for each listed species unless such a plan would not promote its recovery.

NMFS began conducting comprehensive and systematic aerial surveys of the Cook Inlet beluga whale population in 1993. These surveys documented a decline in abundance from 653 whales in 1994 to 347 whales in 1998, a decline of nearly 50 percent. This rapid decline was associated with a substantial, unregulated subsistence hunt. Subsequent cooperative efforts between NMFS and Alaska Native subsistence users dramatically reduced subsistence hunts beginning in 1999. If subsistence harvest was the only factor limiting population growth, this reduction in hunting should have allowed the Cook Inlet beluga whale population to begin recovering at a rate of 2 to 6 percent per year; however, survey data indicated that the population was not recovering upon removal of hunting pressure. This lack of population growth led NMFS to reevaluate the status of Cook Inlet beluga whales. In October 2008, NMFS listed the Cook Inlet beluga whale

distinct population segment (DPS) as endangered under the ESA (73 FR 62919, October 22, 2008). The most recent (2014) abundance survey indicates a population of 340 Cook Inlet beluga whales that has declined 0.4 percent per year over the past ten years.

The Cook Inlet belugas are the most reproductively and demographically isolated of all the Alaskan belugas, and are unique in Alaska because their habitat, a semi-enclosed tidal estuary in southcentral Alaska, is in close proximity to most of Alaska's human population. The distribution of Cook Inlet belugas has changed significantly since the 1970s; in recent years the summer range has contracted to the upper reaches of Cook Inlet near Anchorage. This range contraction was coincident with the decline in population size.

Ten potential threat types are identified and assessed in this draft recovery plan, based on current knowledge of threat factors. Assessments were made based on the information and data gaps presented in the plan's background section. Climate change, while considered a potential threat to Cook Inlet beluga recovery, is not addressed as a separate threat, but rather is discussed with respect to how it may affect each of the listed threats. The ten identified threats were ranked in order of their relative concern (high, medium, low) to the Cook Inlet beluga population.

Due to an incomplete understanding of the threats facing Cook Inlet beluga whales, NMFS is unable to identify with certainty the actions that will most immediately encourage recovery. Until we know which threats are limiting recovery, the strategy of this recovery plan is to focus on threats identified as medium or high concern. This should focus efforts and resources on actions that are more likely to benefit Cook Inlet beluga whale recovery.

Under section 4(f)(1) of the ESA, recovery plans must contain objective, measurable criteria which, when met, would result in a determination that the species be delisted. This recovery plan contains both demographic and threats-based criteria for down- and delisting. The threat-based recovery criteria are designed to evaluate the five ESA section 4(a)(1) factors described in the ESA listing determination of the Cook Inlet belugas. The draft recovery plan proposes that Cook Inlet beluga whales may be reclassified from endangered to threatened (*i.e.,* downlisted) when all of the following have been met: (1) The abundance estimate for the Cook Inlet beluga whale DPS is greater than or equal to 520 individuals and there is 95 percent or greater probability that the 25-year population abundance trend (representative of one full generation) is positive; and (2) the 15 downlisting threats-based criteria are satisfied. The draft recovery plan proposes that the population will be considered for delisting when all of the following are met: (1) The abundance estimate for the Cook Inlet beluga whale DPS is greater than or equal to 780 individuals and there is 95 percent or greater probability that the 25-year population abundance trend (representative of one full generation) is positive; and (2) the 15 downlisting and 6 delisting threats-based criteria are satisfied.

When determining recovery actions, we aimed to improve understanding of whether a particular threat is limiting recovery and to eliminate or mitigate that threat, or to improve our understanding of, and ability to manage, that threat. The actions in this recovery plan include research, management, monitoring, and outreach efforts, since a comprehensive approach to Cook Inlet beluga whale recovery is likely to have greater success than focusing on any one type of action. There are also actions targeted at incorporating new information and conducting regular reassessments, making this recovery plan an adaptive management plan.

The total time and cost to recovery are very difficult to predict with the current information, and the total cost to recovery will be largely dependent upon the number of recovery actions requiring implementation. Since that cannot be determined prior to implementation of portions of this plan, the total cost presented assumes implementation of all recovery actions. As recovery progresses and we better understand the relationship between discrete threats and population dynamics, it may become apparent that there are some threats that need not be addressed to achieve recovery. However, we expect that recovery may take at least two generations (50 years).

If every identified recovery action is implemented, and if recovery implementation lasts for 50 years (two generations), then the estimated cost of implementing this entire recovery program would be approximately $78.3 million. Any projections of total costs over the full recovery period are likely to be imprecise, and the cost estimates do not imply that funding will necessarily be available for all Cook Inlet beluga whale recovery tasks.

NMFS requests and will consider all substantive comments and information presented during the public comment period as we finalize this Plan. NMFS concludes that the Draft Recovery Plan meets the requirements of the ESA.

**Authority:** 16 U.S.C. 1531 *et seq.*

Dated: May 11, 2015.

**Angela Somma,**

*Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–11700 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Availability of Seats for National Marine Sanctuary Advisory Councils

**AGENCY:** Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice and request for applications.

**SUMMARY:** ONMS is seeking applications for vacant seats for 7 of its 13 national marine sanctuary advisory councils and for the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve Advisory Council (advisory councils). Vacant seats, including positions (*i.e.,* primary member and alternate), for each of the advisory councils are listed in this notice under **SUPPLEMENTARY INFORMATION.** Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; views regarding the protection and management of marine or Great Lake resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members or alternates should expect to serve two- or three year terms, pursuant to the charter of the specific national marine sanctuary advisory council or the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve Advisory Council.

**DATES:** Applications are due by June 30, 2015.

**ADDRESSES:** Application kits are specific to each advisory council. As such, application kits must be obtained from and returned to the council-specific addresses noted below.

- Channel Islands National Marine Sanctuary Advisory Council: Michael Murray, Channel Islands National Marine Sanctuary, University of California Santa Barbara, Ocean Science Education Building 514, MC 6155, Santa Barbara, CA, 93106–6155; (805) 893–

6418; email *Michael.Murray@noaa.gov;* or download application from *http://channelislands.noaa.gov/sac/council_news.html.*

• Flower Garden Banks National Marine Sanctuary Advisory Council: Shelley DuPuy, Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551; (409) 621–5151 extension 106; email *Shelley.DuPuy@noaa.gov;* or download application from *http://flowergarden.noaa.gov/advisorycouncil/councilnews.html.*

• Gray's Reef National Marine Sanctuary Advisory Council: Becky Shortland, Gray's Reef National Marine Sanctuary, 10 Ocean Science Circle, Savannah, GA 31411; (912) 598–2381; email *Becky.Shortland@noaa.gov;* or download application from *http://graysreef.noaa.gov/management/sac/council_news.html.*

• Hawaiian Islands Humpback Whale National Marine Sanctuary Advisory Council: Inouye Regional Center, ATTN: NOS/ONMS/Shannon Lyday, 1845 Wasp Blvd., Building 176, Honolulu, HI 96818; (808) 725–5905; email *Shannon.Lyday@noaa.gov;* or download application from *http://hawaiihumpbackwhale.noaa.gov/council/council_app_accepting.html.*

• Monitor National Marine Sanctuary Advisory Council: Katherine Van Dam, Monitor National Marine Sanctuary, 100 Museum Drive, Newport News, VA 23606; (757) 591–7350; email *Katherine.VanDam@noaa.gov;* or download application from *http://monitor.noaa.gov.*

• National Marine Sanctuary of American Samoa Advisory Council: Joseph Paulin, National Marine Sanctuary of American Samoa, Tauese P.F. Sunia Ocean Center, P.O. Box 4318 Pago Pago, American Samoa 96799; (684) 633–6500; email *Joseph.Paulin@noaa.gov;* or download application from *http://americansamoa.noaa.gov.*

• Stellwagen Bank National Marine Sanctuary Advisory Council: Elizabeth Stokes, Stellwagen Bank National Marine Sanctuary, 175 Edward Foster Road, Scituate MA 02066; (781) 545–8026 extension 201; email *elizabeth.stokes@noaa.gov;* or download application from *http://stellwagen.noaa.gov/management/sac/sachome.html.*

**FOR FURTHER INFORMATION CONTACT:** For further information on a particular national marine sanctuary advisory council, please contact the individual identified in the **ADDRESSES** section of this notice.

**SUPPLEMENTARY INFORMATION:** ONMS serves as the trustee for 14 marine protected areas encompassing more than 170,000 square miles of ocean and Great Lakes waters from the Hawaiian Islands to the Florida Keys, and from Lake Huron to American Samoa. National marine sanctuaries protect our Nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustains healthy environments that are the foundation for thriving communities and stable economies. One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. National marine sanctuary advisory councils are community-based advisory groups established to provide advice and recommendations to the superintendents of the national marine sanctuaries on issues including management, science, service, and stewardship; and to serve as liaisons between their constituents in the community and the sanctuary. Additional information on ONMS and its advisory councils can be found at *http://sanctuaries.noaa.gov.* Information related to the purpose, policies and operational requirements for advisory councils can be found in the charter for a particular advisory council (*http://sanctuaries.noaa.gov/management/ac/council_charters.html*) and the National Marine Sanctuary Advisory Council Implementation Handbook (*http://www.sanctuaries.noaa.gov/management/ac/acref.html*).

The following is a list of the vacant seats, including positions (*i.e.,* primary member or alternate), for each of the advisory councils currently seeking applications for members and alternates:

*Channel Islands National Marine Sanctuary Advisory Council: Non-consumptive Recreation (primary); and Non-consumptive Recreation (alternate).*

*Flower Garden Banks National Marine Sanctuary Advisory Council: Recreational Fishing (primary).*

*Gray's Reef National Marine Sanctuary Advisory Council: Conservation (primary); University Education (primary); Sport Diving (primary); and Citizen-at-Large (primary).*

*Hawaiian Islands Humpback Whale National Marine Sanctuary Advisory Council: Commercial Shipping (primary); Commercial Shipping (alternate); Hawaii County (alternate); Lanai Island (alternate); Citizen-at-Large (alternate); Education (alternate); Tourism (alternate); and Whale Watching (alternate).*

*Monitor National Marine Sanctuary Advisory Council: Commercial and Recreational Fishing (primary).*

*National Marine Sanctuary of American Samoa Advisory Council: Business and Industry (primary); and Community-at-Large: Tutuila—West Side (primary).*

*Stellwagen Bank National Marine Sanctuary Advisory Council: At-Large (primary); Business Industry (primary); Diving (primary); Diving (alternate); Education (2 primary seats); Fixed Gear Commercial Fishing (primary); Fixed Gear Commercial Fishing (alternate); Mobile Gear Commercial Fishing (alternate); Recreational Fishing (alternate); Research (2 alternate seats); and Whale Watch (primary).*

**Authority:** 16 U.S.C. Sections 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: April 13, 2015.

**Daniel J. Basta,**

*Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.*

[FR Doc. 2015–11630 Filed 5–14–15; 8:45 am]

BILLING CODE 3510–NK–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling a public meeting of its Habitat Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** This meeting will be held on Monday, June 1, 2015 at 9 a.m.

**ADDRESSES:** The meeting will be held at the Holiday Inn, 300 Woodbury Avenue, Portsmouth, NH 03801; telephone: (603) 431–8000; fax: (603) 501–3733.

*Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

**FOR FURTHER INFORMATION CONTACT:** Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

**SUPPLEMENTARY INFORMATION:** The Habitat Committee will consider data and analyses related to current habitat management alternatives for Georges Bank as part of Omnibus Essential Fish Habitat Amendment 2. These will include analyses related to a new alternative identified during the April Council meeting. The Committee may choose to revise its preferred alternative recommendation for Georges Bank to the full Council. (The Council plans to take final action on Georges Bank habitat management alternatives during its June 16–18, 2015 meeting.)

The Committee may also discuss other matters related to the amendment, in particular the spawning management alternatives. (The spawning alternatives are also planned for final Council action in June.) They will discuss other business as necessary.

Although non-emergency issues not contained in this agenda may come before these groups 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 Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

**Special Accommodations**

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: May 12, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–11758 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD939**

### Marine Mammals; File No. 19526

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that Adam White, BBC Natural History Unit, The Limes, Lea, Malmesbury Wiltshire, SN16 9PG United Kingdom, has applied in due form for a permit to conduct commercial or educational photography on four species of cetaceans and five species of pinnipeds.

**DATES:** Written, telefaxed, or email comments must be received on or before June 15, 2015.

**ADDRESSES:** These documents are available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 19526 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Carrie Hubard or Jennifer Skidmore, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film a variety of marine mammals along the California coast from Point Año Nuevo south to the Channel Islands. A maximum of 1000 long-beaked common dolphins (*Delphinus capensis*), 1000 short-beaked common dolphins (*Delphinus delphis*), 1000 Risso's dolphins (*Grampus griseus*), 50 bottlenose dolphins (*Tursiops truncatus*), 50 harbor seals (*Phoca vitulina*), and 1000 California sea lions (*Zalophus californianus*) would be approached for filming. In addition, up to 200 Northern elephant seals (*Mirounga angustirostris*) would be filmed while hauled out on land. Fifty Steller sea lions (*Eumetopias jubatus*) and 50 Northern fur seals (*Callorhinus ursinus*) may be incidentally harassed and filmed during operations. Cetaceans would be filmed from boats and pole cameras. Pinnipeds would be filmed from boats, pole cameras, underwater divers, and while hauled out on land. Hydrophones would be used to record sounds. Footage would be used for a *Big Blue Live* television series examining marine issues and conservation successes along the coast of California. Filming would occur July through September 2015. The permit would be valid until September 30, 2015.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 8, 2015.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–11753 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Telecommunications and Information Administration

### First Responder Network Authority; First Responder Network Authority Board Meetings

**AGENCY:** First Responder Network Authority (FirstNet), U.S. Department of Commerce.

**ACTION:** Notice of public meetings.

**SUMMARY:** The Board of the First Responder Network Authority (FirstNet) will convene an open public meeting on June 3, 2015, preceded by open public meetings of the Board Committees on June 2, 2015.

**DATES:** On June 2, 2015 between 9:00 a.m. and 6:00 p.m. Pacific Daylight Time, there will be sequential open public meetings of FirstNet's four Board Committees: (1) Governance and Personnel; (2) Technology; (3) Outreach; and (4) Finance. The full FirstNet Board will hold an open public meeting on June 3, 2015 between 8:00 a.m. and 10:00 a.m. Pacific Daylight Time.

**ADDRESSES:** The meetings on June 2 and June 3, 2015 will be held at the Omni San Diego Hotel, 675 L Street, San Diego, CA 92101.

**FOR FURTHER INFORMATION CONTACT:** Uzoma Onyeije, Secretary, FirstNet, 12201 Sunrise Valley Drive, M/S 243,

Reston, VA 20192; telephone: (703) 648–4165; email: *uzoma.onyeije@firstnet.gov*. Please direct media inquiries to Ryan Oremland at (703) 648–4114.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Board of FirstNet will convene an open public meeting on June 3, 2015, preceded by open public meetings of the Board Committees on June 2, 2015.

*Background:* The Middle Class Tax Relief and Job Creation Act of 2012 (Act), Public Law 112–96, 126 Stat. 156 (2012), established FirstNet as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs FirstNet to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's operations. The FirstNet Board held its first public meeting on September 25, 2012.

*Matters to be Considered:* FirstNet will post detailed agendas of each meeting on its Web site, *http://www.firstnet.gov, prior* to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Committees and the Board may involve commercial or financial information that is privileged or confidential, personnel matters, or other legal matters affecting FirstNet. As such, the Committee Chairs and Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

*Times and Dates of Meetings:* On June 2, 2015, between 9:00 a.m. and 6:00 p.m. Pacific Daylight Time, there will be sequential open public meetings of FirstNet's four committees. The open public meeting of the full FirstNet Board will be held on June 3, 2015, between 8:00 a.m. and 10:00 a.m. Pacific Daylight Time.

*Place:* The meetings on June 2 and June 3, 2015 will be held at the Omni San Diego Hotel, 675 L Street, San Diego, CA 92101.

*Other Information:* These meetings are open to the public and press on a first-come, first-served basis. Space is limited. In order to get an accurate headcount, all expected attendees are asked to provide notice of intent to attend by sending an email to *BoardRSVP@firstnet.gov*. If the number of RSVPs indicates that expected attendance has reached capacity, FirstNet will respond to all subsequent notices indicating that capacity has been reached and that in-person viewing may no longer be available but that the meeting may still be viewed by webcast as detailed below. For access to the meetings, valid government issued photo identification may be requested for security reasons.

The meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Uzoma Onyeije, Secretary, FirstNet, at (703) 648–4165 or *uzoma.onyeije@firstnet.gov,* at least five (5) business days before the applicable meeting(s).

The meetings will also be webcast. Please refer to FirstNet's Web site at *www.firstnet.gov* for webcast instructions and other information. The meetings will also be available to interested parties by phone. To be connected to the meetings in listen-only mode by telephone, please dial (888) 997–9859 and passcode 3572169. If you have technical questions regarding the webcast, please contact Margaret Baldwin at (703) 648–4161 or by email at *margaret.baldwin@firstnet.gov*.

*Records:* FirstNet maintains records of all Board proceedings. Minutes of the Board Meeting and the Committee meetings will be available at *www.firstnet.gov*.

Dated: May 12, 2015.

**Eli Veenendaal,**

*Attorney Advisor, First Responder Network Authority.*

[FR Doc. 2015–11778 Filed 5–14–15; 8:45 am]

**BILLING CODE 3510–TL–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List Proposed Addition and Deletions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Proposed addition to and deletions from the Procurement List.

**SUMMARY:** The Committee is proposing to add a service to the Procurement List that will be provided by nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products previously furnished by such agencies.

*Comments Must Be Received on or Before:* 6/15/2015.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

**FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT:** Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

### Addition

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to procure the service listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following service is proposed for addition to the Procurement List for production by the nonprofit agency listed:

*Service*

*Service Type:* Third Party Logistics Service
*Service Is Mandatory For:* U.S. Department of State P.O. Box 9115, Rosslyn Station, Arlington, VA
*Mandatory Source of Supply:* Human Technologies Corporation, Utica, NY
*Contracting Activity:* Department of State, Office of Acquisition Management—MA, Arlington, VA

### Deletions

The following products are proposed for deletion from the Procurement List:

*Products*

*Product Name/NSN(s):* Cushion, Chair, 7210–00–205–3544, 7210–00–205–3545
*Mandatory Source of Supply:* UNKNOWN
*Contracting Activity:* General Services Administration, Fort Worth, TX

*Product Name/NSN(s):* Cushion Seat, Vehicular, 2540–00–904–5680
*Mandatory Source of Supply:* The Douglas Center, Skokie, IL
*Contracting Activity:* Defense Logistics Agency Land and Maritime, Columbus, OH

*Product Name/NSN(s):* Stay Put Elastics Asst/MR 3202, Fashion Bobby Pin/MR 3216
*Mandatory Source of Supply:* Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY
*Contracting Activity:* Defense Commissary Agency, Fort Lee, VA

*Product Name/NSN(s):* Duster, Lambswool/MR 992
*Mandatory Source of Supply:* Industries of the Blind, Inc., Greensboro, NC
*Contracting Activity:* Defense Commissary

Agency, Fort Lee, VA

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2015–11755 Filed 5–14–15; 8:45 am]

**BILLING CODE 6353–01–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; Initial Certification

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Notice; request for comments.

**SUMMARY:** Committee for Purchase From People Who Are Blind or Severely Disabled (Committee) will submit the collection of information listed below to OMB for approval under the provisions of the Paperwork Reduction Act. This notice solicits comments on this collection of information.

**DATES:** Submit your written comments on the information collection on or before July 15, 2015.

**ADDRESSES:** Mail your comments on the requirement to Lou Bartalot, Director Compliance, Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, VA 22202–4149; fax (703) 603–0655; or email *rulecomments@abilityone.gov.*

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the applicable forms or explanatory material, contact Edward Yang at the address in the above paragraph or through the above email address.

**SUPPLEMENTARY INFORMATION:** The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). The Committee plans to submit a request to OMB to approve a revised collection of information concerning annual certification of nonprofit agencies serving people who are blind or who have other significant disabilities to participate in the AbilityOne Program. The Committee is requesting a 3-year term of approval for this information collection activity.

Federal agencies 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 the current collections of information are 3037–0001 and 3037–0002. The OMB control number for the revised collection of information is 3037–0013.

The JWOD Act of 1971 (41 U.S.C. 8501–8506) is the authorizing legislation for the AbilityOne Program. The AbilityOne Program creates jobs and training opportunities for people who are blind or who have other severe disabilities. Its primary means of doing so is by requiring Government agencies to purchase selected products and services from nonprofit agencies employing such individuals. The AbilityOne Program is administered by the Committee. Two national, independent organizations, National Industries for the Blind (NIB) and SourceAmerica, help State and private nonprofit agencies participate in the AbilityOne Program.

The implementing regulations for the JWOD Act, which are located at 41 CFR Chapter 51, provide the requirements, procedures, and standards for the AbilityOne Program. Section 51–4.3 of the regulations sets forth the standards that a nonprofit agency must meet to maintain qualification for participation in the AbilityOne Program. Under this section of the regulations, a nonprofit agency that wants to continue to participate in the AbilityOne Program must submit a completed copy of the appropriate Annual Certification form (Committee Form 403 or 404). This documentation helps the Committee determine whether the applicant nonprofit agency is meeting the requirements of the AbilityOne Program.

This information collection request seeks approval for the Committee to continue to collect the information required under 41 CFR 51–4.3 of the regulations, but in a revised and expanded format, so that the Committee can continue to verify the appropriateness of nonprofit agencies that would like to participate in the AbilityOne Program. The previous separate forms have been combined into one form. The items being certified have been revised to match the regulatory requirements of section 51–4.3 and to collect other pertinent information on the qualifications of nonprofit agencies. New questions concerning nonprofit agency hours, wages, people performing direct labor, subcontracting and veterans have been added. In addition, the language at the bottom of the certification section has been revised.

*Title:* Annual Representations and Certifications For AbilityOne Qualified Nonprofit Agency.

*OMB Control Number:* 3037–0013.

*Form Number:* Reps and Certs.

*Description of Respondents:* Nonprofit agencies serving people who are blind or significantly disabled that participate in the AbilityOne Program.

*Annual Number of Respondents:* About 570 nonprofit agencies serving people who are blind or significantly disabled will annually participate in the AbilityOne Program.

*Total Annual Burden Hours:* Burden is estimated to average 8 hours per respondent. Total annual burden is 4,560 hours. Note: this burden estimate is only for the reporting of information; a separate burden estimate exists for the recordkeeping requirement.

We invite comments concerning this renewal on: (1) Whether the collection of information is necessary for the proper performance of our agency's functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents.

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2015–11754 Filed 5–14–15; 8:45 am]

**BILLING CODE 6353–01–P**

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0092, Customer Clearing Documentation and Timing of Acceptance for Clearing

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. The Commission adopted final rules, which prohibit

swap dealers (''SDs'') and major swap participants (''MSPs'') from interfering or attempting to influence the decisions of affiliated future commission merchants (''FCMs'') with regard to the provision of clearing services and activities and prohibit FCMs from permitting them to do so. The Commission also adopted rules to prohibit SDs and MSPs from adopting any process or taking any action that results in any unreasonable restraint on trade or imposes any material anticompetitive burden on trading or clearing, unless necessary or appropriate to achieve the purposes of the Commodity Exchange Act. The Commission adopted further rules requiring that derivatives clearing organization (''DCO'') rules provide for the non-discriminatory clearing of swaps executed bilaterally or through an unaffiliated designated contract market or swap execution facility. This notice solicits comments on the obligation to maintain records related to clearing documentation between the customer and the customer's clearing member.

**DATES:** Comments must be submitted on or before July 14, 2015.

**ADDRESSES:** You may submit comments, identified by OMB Control No. 3038–0092, by any of the following methods:

- The Agency's Web site, at *http://comments.cftc.gov/*. Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.
- *Federal eRulemaking Portal: http://www.regulations.gov/*. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

**FOR FURTHER INFORMATION CONTACT:** Christopher Hower, Special Counsel, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; (202) 418–6703; email: *chower@cftc.gov*.

**SUPPLEMENTARY INFORMATION:** Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

*Title:* Customer Clearing Documentation and Timing of Acceptance for Clearing (OMB Control No. 3038–0092). This is a request for extension of a currently approved information collection.

*Abstract:* Section 4d(c) of the Commodity Exchange Act (''CEA'' or ''Act''), as amended by the Dodd-Frank Act, directs the Commission to require futures commission merchants to implement conflict of interest procedures that address such issues the Commission determines to be appropriate. Similarly, section 4s(j)(5), as added by the Dodd-Frank Act, requires swap dealers and major swap participants to implement conflict of interest procedures that address such issues the Commission determines to be appropriate. Section 4s(j)(5) also requires swap dealers and major swap participants to ensure that any persons providing clearing activities or making determinations as to accepting clearing customers are separated by appropriate informational partitions from persons whose involvement in pricing, trading, or clearing activities might bias their judgment or contravene the core principle of open access. Section 4s(j)(6) of the CEA prohibits a swap dealer and major swap participant from adopting any process or taking any action that results in any unreasonable restraint on trade or imposes any material anticompetitive burden on trading or clearing, unless necessary or appropriate to achieve the purposes of the Act. Section 2(h)(1)(B)(ii) of the CEA requires that derivatives clearing organization rules provide for the non-discriminatory clearing of swaps executed bilaterally or through an unaffiliated designated contract market or swap execution facility.

Pursuant to these provisions, the Commission adopted § 1.71(d)(1) relating to FCMs and § 23.605(d)(1) relating to swap dealers and major swap participants. These regulations prohibit swap dealers and major swap participants from interfering or attempting to influence the decisions of affiliated FCMs with regard to the provision of clearing services and activities and would prohibit FCMs from permitting them to do so. The Commission also adopted § 23.607 to prohibits a swap dealer and major swap participant from adopting any process or taking any action that results in any unreasonable restraint on trade or imposes any material anticompetitive burden on trading or clearing, unless necessary or appropriate to achieve the purposes of the Act. The Commission adopted § 39.12(b)(2) to require that derivatives clearing organization rules provide for the non-discriminatory clearing of swaps executed bilaterally or through an unaffiliated designated contract market or swap execution facility.

As discussed further below, the additional information collection burden arising from the regulations primarily is restricted to the costs associated with the affected registrants' obligation to maintain records related to clearing documentation between the customer and the customer's clearing member.

The information collection obligations imposed by the regulations are necessary to implement certain provisions of the CEA, including ensuring that registrants exercise effective risk management and for the efficient operation of trading venues among SDs, MSPs, FCMs, and DCOs.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov*. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for

confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

*Burden Statement:* The respondent burden for this collection is estimated to average between 16 hours for FCMs and SDs and MSPs, and 40 hours for DCOs per response. This estimate includes the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a federal agency. The total annual cost burden per respondent is estimated to be $736 for FCMs, SDs, and MSPs and $1,840 for DCOs. The Commission based its calculation on an hourly wage rate of $46 for a financial manager to maintain the data.

*Respondents/Affected Entities:* Swap dealers, Major Swap Participants, Futures Commission Merchants, and Derivatives Clearing Organizations.

*Estimated number of respondents:* 239 Swap Dealers, Major Swap Participants and Futures Commission Merchants, and 14 Derivatives Clearing Organizations.

*Estimated total annual burden on respondents:* 3,824 for FCMs, SDs, and MSPs, and 560 hours for DCOs.

*Frequency of collection:* As needed.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: May 11, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015–11726 Filed 5–14–15; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Transmittal No. 15–22]**

### 36(b)(1) Arms Sales Notification

**AGENCY:** Defense Security Cooperation Agency, Department of Defense.

**ACTION:** Notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15–22 with attached transmittal, and policy justification.

Dated: May 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 28 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-22, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Australia for defense articles and services estimated to cost $1.5 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

for J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 15–22

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Australia

(ii) *Total Estimated Value:*

| | |
|---|---|
| Major Defense Equipment * .. | $0.00 billion |
| Sustainment ..... | $1.50 billion |
| Total ..... | $1.50 billion |

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* follow-on sustainment support and services for twenty four (24) AF/A–18Fs Super Hornet and twelve (12) AEA–18G Growler aircraft. The sustainment efforts will include software and hardware updates, Engineering Change Proposals, System Configuration upgrades, system integration and testing, engine component improvement, tools and test equipment, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, aircrew trainer devices upgrades, U.S. Government and contractor technical assistance, and other related elements of logistics and program support.

(iv) *Military Department:* Navy (GQF)

(v) *Prior Related Cases, if any:*

FMS case SAF–$2.2B–02May07

FMS case GQY–$358M–6May11

FMS case LEN–$992M–13Sep12

FMS case SCI–$1.3B–04Jul13

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 28 April 2015

* as defined in Section 47(6) of the Arms Export Control Act.

*POLICY JUSTIFICATION*

*Australia—F/A–18E/F Super Hornet and EA–18G Growler Aircraft Sustainment*

The Government of Australia has requested a possible sale of follow-on sustainment support and services for twenty four (24) AF/A–18Fs Super Hornet and twelve (12) AEA–18G Growler aircraft. The sustainment efforts will include software and hardware updates, Engineering Change Proposals, System Configuration upgrades, system integration and testing, engine component improvement, tools and test equipment, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, aircrew trainer devices upgrades, U.S. Government and contractor technical assistance, and other related elements of logistics and program support. The estimated cost is $1.5 billion.

This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major contributor to political stability, security, and economic development in Southeast Asia and around the world. Australia is an important ally and partner that contributes significantly to coalition, peacekeeping, and humanitarian operations around the world. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability. This proposed sale is consistent with those objectives and facilitates burden sharing with a key ally.

The proposed sale of follow-on sustainment support and services will enable the Royal Australian Air Force to ensure the reliability and performance of its F/A–18 fleet. The follow-on support will allow Australia to maintain aircraft availability/operational rates, and enhance interoperability with the U.S. and other nations.

The proposed sale of this additional support will not alter the basic military balance in the region.

The principal contractor will be The Boeing Company in St. Louis, Missouri. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale may require continued assignment of U.S. Government and contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2015–11723 Filed 5–14–15; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Transmittal No. 15–15]**

### 36(b)(1) Arms Sales Notification

**AGENCY:** Defense Security Cooperation Agency, Department of Defense.

**ACTION:** Notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15–15 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: May 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 24 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-15, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to India for defense articles and services estimated to cost $96 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 15–15

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* India

(ii) *Total Estimated Value:*

| | |
|---|---|
| Major Defense Equipment * .. | $ 8.0 million |
| Other ..... | $88.0 million |
| TOTAL ..... | $96.0 million |

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* follow on support for five years for their fleet of C–130J Super Hercules that includes 8 spare AN/ALE–47 Counter-Measures Dispensing Systems, 6 spare AN/ALR–56M Advanced Radar Warning Receivers, up to 9,000 flare cartridges, spare and repair parts, configuration updates, support and test equipment, publications and technical data, technical services, personnel training and training equipment, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support

(iv) *Military Department:* Air Force (QAE)

(v) *Prior Related Cases, if any:* FMS Case SAA -$963M –21Feb08

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 24 Apr 15

* As defined in Section 47(6) of the Arms Export Control Act.

*POLICY JUSTIFICATION*

*India—Follow-on Support of C–130J Super Hercules Aircraft*

The Government of India has requested a possible sale for follow on support for five years for their fleet of C–130J Super Hercules that includes 8 spare AN/ALE–47 Counter-Measures Dispensing Systems, 6 spare AN/ALR–56M Advanced Radar Warning Receivers, up to 9,000 flare cartridges, spare and repair parts, configuration updates, support and test equipment, publications and technical data, technical services, personnel training and training equipment, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support. The estimated cost is $96.0 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to strengthen the U.S.-India strategic relationship and to improve the capabilities of a major South Asian partner which has been, and continues to be, an important force for economic progress and stability in South Asia.

India needs this support for its Super Hercules aircraft to ensure its aircraft operate effectively to serve its transport, local and international humanitarian assistance, and regional disaster relief needs. This proposed sale of additional equipment and support will enable the Indian Air Force to sustain a higher mission-ready status for its C–130J fleet.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be the Lockheed-Martin Company in Marietta, Georgia. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor personnel to India.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 15–15

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AN/ALR–56M is a computer controlled radar warning receiver (RWR). It monitors the environment in an effort to detect radar signals. Upon detection and identification of a valid radar signal, emitter identification is conveyed to the AN/ALE–47 countermeasures dispenser system. The ALR–56M has thirteen line replaceable units (LRUs): four I/J band DF receivers, an Analysis Processor, a Superhet Controller, a Superhet Receiver, a C/D band Receiver/Power supply, four I/J band antennas, and one C/D band antenna. Hardware and software are classified up to Confidential. Technical data and documentation are classified up to Secret.

2. The AN/ALE–47 Counter-Measures Dispensing System (CMDS) is an integrated, threat-adaptive, software-programmable dispensing system capable of dispending chaff, flares, and active radio frequency expendables. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board electronic warfare and avionics systems. The AN/ALE–47 uses data received over the aircraft interfaces to assess the threat situation and to determine a response. Hardware and software are Unclassified. Technical data and documentation are classified up to Secret.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. The sale is necessary in furtherance of the U.S. foreign policy and national security objectives outline in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of India.

[FR Doc. 2015–11714 Filed 5–14–15; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Transmittal Nos. 15–19]**

### 36(b)(1) Arms Sales Notification

**AGENCY:** Department of Defense, Defense Security Cooperation Agency.

**ACTION:** Notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15–19 with attached transmittal and policy justification.

Dated: May 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 05 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-19, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost $395 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 15–19

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Iraq

(ii) *Total Estimated Value:*

| | |
|---|---|
| Major Defense Equipment * .. | $ 70 million |
| Other ..... | $325 million |
| TOTAL ..... | $395 million |

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 5,000 81mm High Explosive Mortar Ammunition, 684,000 M203 40mm High Explosive Ammunition, 532,000 MK19 40mm High Explosive Dual Purpose Ammunition, and 40,000 155mm High Explosives. Also includes small arms ammunition, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Army (UHA)

(v) *Prior Related Cases, if any:*

FMS case UGB–$17M–28Jan14

FMS case UEL–$70M–18Jun12

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 05 May 2015

* As defined in Section 47(6) of the Arms Export Control Act.

*POLICY JUSTIFICATION*

*Iraq—Ammunition*

The Government of Iraq has requested a possible sale of 5,000 81mm High Explosive Mortar Ammunition, 684,000 M203 40mm High Explosive Ammunition, 532,000 MK19 40mm High Explosive Dual Purpose Ammunition, and 40,000 155mm High Explosives. Also includes small arms ammunition, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical and logistics support services, and other related elements of logistical and program support. The estimated cost is $395 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a strategic partner. This proposed sale directly supports the Government of Iraq and serves the interests of the people of Iraq and the United States.

This proposed sale of additional ammunition is critical in providing continued combat power capability as Iraq continues its fight against an organized insurgency of extremists in Iraq. Iraq will have no difficulty absorbing this additional ammunition into its armed forces.

The proposed sale of this additional ammunition will not alter the basic military balance in the region.

The principal contractors will be American Ordinance in Middletown, Iowa and AMTEC in Janesville, Wisconsin. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will not require U.S. Government representatives or contractors to travel to Iraq.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2015–11719 Filed 5–14–15; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID: DoD–2015–OS–0048]**

### Proposed Collection; Comment Request

**AGENCY:** Defense Security Service (DSS), DoD.

**ACTION:** Notice.

**SUMMARY:** In compliance with the *Paperwork Reduction Act of 1995,* the Defense Security Service (DSS) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by July 14, 2015.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

*Instructions:* All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Security Service, ATTN: Mr. Robert C. Morton, OCIO, Russell-Knox Building, 27130 Telegraph Road, Quantico, VA 22134–2253, or call Defense Security Service, (571) 305–6442.

**SUPPLEMENTARY INFORMATION:**

*Title; Associated Form; and OMB Number:* ''Department of Defense Security Agreement,'' ''Appendage to Department of Defense Security Agreement,'' ''Certificate Pertaining to Foreign Interests;'' DD Forms, 441, 441–1 and SF 328; OMB No. 0704–0194.

*Needs and Uses:* Executive Order (EO) 12829 as amended, ''National Industrial Security Program (NISP),'' stipulates that the Secretary of Defense shall serve as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access, to or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The specific requirements necessary to protect classified information released to private industry are set forth in Department of Defense (DoD) 5220.22M, ''National Industrial Security Program Operating Manual (NISPOM),'' dated February 28, 2006 as amended by Conforming Change 1, dated March 28, 2013. These forms are mandated in the Industrial Security Regulation DoD 5220.22–R dated December 1985 as amended, DoD 5220.22—NISP Volume 3, dated April 17, 2014 and The Federal Acquisition Regulation. Respondents must execute DD Form 441, ''Department of Defense Security Agreement,'' which is the initial agreement between the contractor and the government regarding security requirements necessary to protect classified information associated with the contract. This legally binding document details the responsibility of both parties and obligates the contractor to fulfill the requirements outlined in DoD 5220.22M. The DD Form 441–1, ''Appendage to Department of Defense Security Agreement,'' is used to extend the agreement to branch offices of the contractor. The SF Form 328, ''Certificate Pertaining to Foreign Interests,'' must be submitted to provide certification regarding elements of Foreign Ownership, Control or Influence (FOCI) as stipulated in paragraph 2–302 of the NISPOM.

DSS proposes to make changes to the DD Form 441 and SF 328. The requirement for execution of the corporate ''Certificate'' section and the use of a corporate seal is being deleted. Currently the government does not require all corporations to execute the corporate Certificate portion of the Forms. Only those corporations who are in possession of a seal were being required to execute the Certificate. Corporations that do not have a seal and other types of businesses structures

such as limited liability companies, partnership and sole proprietors are only required to have the signing of the agreement witnessed. DSS proposes that a witness is sufficient for all companies whether or not they are a corporation.

*Affected Public:* Business, other profit, and non-profit organizations under DoD Security Cognizance.

*DD 441 Total Annual Burden Hours:* 698.13.

*DD Form 441 Number of Respondents:* 2,992.

*Total DD Form 441 Responses:* 2,992.

*Average Burden Hours per Respondent:* 14 minutes.

*Number of Responses per Respondent:* 1.

*DD Form 441–1 Total Annual Burden Hours:* 171.5.

*Total DD Form 441–1 Respondents:* 1,029.

*Total DD Form 441–1 Responses:* 1,029.

*Average Burden Hours per Respondent:* 10 minutes.

*Number of Responses per Respondent:* 1.

*SF 328 Total Annual Burden Hours:* 3,301.67.

*Total SF 328 Respondents:* 2,830.

*Total SF 328 Responses:* 2,830.

*Averge Burden Hours per Respondent:* 1 hour 10 minutes or 70 MINUTES.

*Number of Responses per Respondent:* 1.

*Combined Total Number of Respondents:* 6,851.

*Combined Total Number of Responses:* 6,851.

*Combined Total Burden Hours:* 4,171.3.

*Combined Total Burden Hours per Respondent:* 1.5 or 94 minutes.

*Frequency:* On occasion.

The execution of the DD Form 441, 441–1 and SF 328 is a factor in making a determination as to whether a contractor company is eligible to have a facility security clearance. It is also a legal basis for imposing NISP security requirements on eligible contractors. These requirements are necessary in order to preserve and maintain the security of the United States through establishing standards to prevent the improper disclosure of classified information.

Dated: May 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2015–11671 Filed 5–14–15; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Transmittal No. 15–26]**

### 36(b)(1) Arms Sales Notification

**AGENCY:** Defense Security Cooperation Agency, Department of Defense.

**ACTION:** Notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15–26 with attached transmittal, and policy justification.

Dated: May 11, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 28 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-26, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Australia for defense articles and services estimated to cost $275 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

for J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 15–26

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Australia

(ii) *Total Estimated Value:*

| | |
|---|---|
| Major Defense Equipment * .. | $ 0 million |
| Sustainment ..... | $275 million |
| Total ..... | $275 million |

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* follow-on sustainment support and services in support of three (3) Hobart Class Destroyers. The sustainment efforts will include AEGIS computer software and hardware updates, system integration and testing, tools and test equipment, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, aircrew trainer devices upgrades, U.S. Government and contractor technical assistance, and other related elements of logistics and program support.

(iv) *Military Department:* Navy (GSU)

(v) *Prior Related Cases, if any:* FMS case LCQ–$1.2B–17Nov05

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 28 April 2015

* as defined in Section 47(6) of the Arms Export Control Act.

*POLICY JUSTIFICATION*

*Australia—Hobart Class Destroyer Sustainment*

The Government of Australia has requested a possible sale of follow-on sustainment support and services in support of three (3) Hobart Class Destroyers. The sustainment efforts will include AEGIS computer software and hardware updates, system integration and testing, tools and test equipment, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, aircrew trainer devices upgrades, U.S. Government and contractor technical assistance, and other related elements of logistics and program support. The estimated cost is $275 million.

This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major contributor to political stability, security, and economic development in Southeast Asia. Australia is an important ally and partner that contributes significantly to coalition, peacekeeping and humanitarian operations around the world. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability. This proposed sale is consistent with those objectives and facilitates burden sharing with a key ally.

The proposed sale will improve Australia's capability in current and future coalition efforts. Australia will use the enhanced capability as a deterrent to regional threats and to strengthen its homeland defense. Australia will have no difficulty absorbing this additional support into its armed forces.

The proposed sale of this additional support will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin Mission Systems and Training in Washington, District of Columbia. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the temporary assignment of approximately five U.S. Government or contractor representatives for a period of three years to Australia on an intermittent basis for the life of the case.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2015–11725 Filed 5–14–15; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2015–ICCD–0064]**

### Agency Information Collection Activities; Comment Request; Health Education Assistance Loan (HEAL) Program: Forms

**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before July 14, 2015.

**ADDRESSES:** Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0064 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Health Education Assistance Loan (HEAL) Program: Forms.

*OMB Control Number:* 1845–0128.

*Type of Review:* A revision of an existing information collection.

*Respondents/Affected Public:* Individuals or Households, Private Sector.

*Total Estimated Number of Annual Responses:* 167.

*Total Estimated Number of Annual Burden Hours:* 24.

*Abstract:* The Health Education Assistance Loan (HEAL) forms are required for lenders to make application to the HEAL insurance program, to report accurately and timely on loan actions, including transfer of loans to a secondary agent, and to establish the repayment status of borrowers who qualify for deferment of payments using form 508. The reports assist in the diligent administration of the HEAL program, protecting the financial interest of the federal government.

Dated: May 11, 2015.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–11691 Filed 5–14–15; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Paducah

**AGENCY:** Department of Energy (DOE).

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Thursday, June 18, 2015, 6:00 p.m.

**ADDRESSES:** Barkley Centre, 111 Memorial Drive, Paducah, Kentucky 42001.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, 1017 Majestic Drive, Suite 200, Lexington, Kentucky 40513, (270) 441–6820.

**SUPPLEMENTARY INFORMATION:**

*Purpose of the Board:* The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management and related activities.

*Tentative Agenda:*

- Call to Order, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Breaks Taken As Appropriate

*Public Participation:* The EM SSAB, Paducah, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Woodard as soon as possible in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jennifer Woodard at the telephone number listed above. Requests must be received as soon as possible prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above. This notice is being published less than 15 days prior to the meeting date due to programmatic issues that had to be resolved prior to the meeting date.

*Minutes:* Minutes will be available by writing or calling Jennifer Woodard at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.pgdpcab.energy.gov/2015Meetings.html.*

Issued at Washington, DC, on May 7, 2015.

**LaTanya R. Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2015–11788 Filed 5–14–15; 8:45 am]

BILLING CODE 6450–01–P

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL15–64–000]**

### New York Public Service Commission, New York Power Authority, New York State Energy Research, and Development Authority v. New York Independent System Operator, Inc.; Notice of Complaint

Take notice that on May 8, 2015, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824(e) and 825(e) and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, the New York Public Service Commission, the New York Power Authority, and the New York State Energy Research and Development Authority (Complainants), filed a formal complaint against the New York Independent System Operator, Inc. (Respondent), alleging that the Respondent's buyer-side market power mitigation measures contained in section 23.4 of Attachment H of the Respondent's Market Administration and Control Area Services Tariff are unjust, unreasonable, and unduly discriminatory and preferential.

The Complainants certify that a copy of the complaint has been served on the Respondent.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic 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 email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5:00 p.m. Eastern Time on May 28, 2015.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11776 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2067–060]**

### Tri-Dam Project; Notice of Application and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Shoreline Management Plan (SMP).

b. *Project No:* 2067–060.

c. *Date Filed:* April 30, 2015.

d. *Applicant:* Tri-Dam Project.

e. *Name of Project:* Tulloch Project.

f. *Location:* The project is located on the main stem of the Stanislaus River in Calaveras and Tuolumne counties, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Susan Larson, Tri-Dam Project, P.O. Box 1158, Pinecrest, CA 95364–0158, (209) 785–3838.

i. *FERC Contact:* Any questions on this notice should be addressed to Shana High at (202) 502–8674, or by email: *shana.high@ferc.gov.*

j. *Deadline for filing comments and/or motions:* June 11, 2015.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and four copies to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–2067–060) on any comments, motions, or recommendations filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Proposal:* Tri-Dam filed its proposed SMP pursuant to article 411 of its license. The proposed SMP provides an inventory of sensitive environmental resources within the project boundary (natural and cultural), maps of sensitive zones that should be afforded extra protection, strategies to protect these areas from inappropriate encroachment, and provisions for informing private shoreline landowners about the importance of protecting the zones identified as having sensitive environmental resources.

Private property owners hold fee title to real property which is adjacent to, abuts, and lies underneath portions of Tulloch Reservoir. Tri-Dam's proposed SMP affects only lands owned or controlled by the licensee. Property rights on privately-owned land are not being altered by this proceeding.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (P–2067) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11772 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC15–136–000.

*Applicants:* BTMU Capital Leasing & Finance, Inc.

*Description:* Application of BTMU Capital Leasing & Finance, Inc. for authorization under Section 203 of the Federal Power Act and Request For expedited Action.

*Filed Date:* 5/11/15.

*Accession Number:* 20150511–5054.

*Comments Due:* 5 p.m. ET 6/1/15.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10–2074–004; ER10–2097–006.

*Applicants:* Kansas City Power & Light Company, KCP&L Greater Missouri Operations Company.

*Description:* Notice of Non-Material Change in Status of Kansas City Power & Light Company, et al.

*Filed Date:* 5/8/15.

*Accession Number:* 20150508–5207.

*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER10–2488–010.

*Applicants:* Oasis Power Partners, LLC.

*Description:* Notice of Non-Material Change of Status of Oasis Power Partners, LLC.

*Filed Date:* 5/8/15.

*Accession Number:* 20150508–5240.

*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER11–47–005; ER12–1540–003; ER12–1541–003; ER12–1542–003; ER12–1544–003; ER10–2981–005; ER14–2475–002; ER14–2476–002; ER14–2477–002; ER11–46–008; ER14–594–005; ER10–2975–008; ER11–41–005; ER12–2343–003; ER13–1896–008.

*Applicants:* Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Wheeling

Power Company, AEP Texas Central Company, AEP Texas North Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, Ohio Power Company, AEP Energy Partners, Inc., CSW Energy Services, Inc., AEP Retail Energy Partners LLC, AEP Energy, Inc., AEP Generation Resources Inc.

*Description:* Notice of Non-Material Change in Status of the AEP MBR Companies.

*Filed Date:* 5/8/15.

*Accession Number:* 20150508–5246.

*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER12–2310–004.

*Applicants:* Zephyr Wind, LLC.

*Description:* Compliance filing per 35: Compliance to 3 to be effective 5/9/2015.

*Filed Date:* 5/11/15.

*Accession Number:* 20150511–5002.

*Comments Due:* 5 p.m. ET 6/1/15.

*Docket Numbers:* ER15–1691–000.

*Applicants:* Duke Energy Progress, Inc.

*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to RS 200 FRPPA NCEMPA to be effective 12/10/2014.

*Filed Date:* 5/11/15.

*Accession Number:* 20150511–5050.

*Comments Due:* 5 p.m. ET 6/1/15.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES15–30–000.

*Applicants:* The United Illuminating Company.

*Description:* Application requesting authorization to issue short-term debt securities in an amount not to exceed $400 million of The United Illuminating Company.

*Filed Date:* 5/8/15.

*Accession Number:* 20150508–5243.

*Comments Due:* 5 p.m. ET 5/29/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 11, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–11766 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 13570–002]**

### Warmsprings Irrigation District; Notice of Effectiveness of Withdrawal of License Application

On April 15, 2013, the Warmsprings Irrigation District (District) filed a license application for an original major project—existing dam for the proposed Warm Springs Dam Hydroelectric Project No. 13570–002. On April 14, 2015, the District filed a letter informing the Commission that it was withdrawing its license application for the project due to unforeseen costs to connect to the grid.

No motion in opposition to the notice of withdrawal has been filed, and the Commission has taken no action to disallow the withdrawal. Pursuant to Rule 216(b) of the Commission's Rules of Practice and Procedure, the withdrawal of the application became effective April 29, 2015 and this proceeding is hereby terminated.[1]

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11773 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. PR15–26–000]**

### Enterprise Texas Pipeline LLC; Notice of Staff Protest To Petition for Rate Approval

1. Commission staff hereby protests pursuant to the section 284.123(g)(4)(i) of the Commission's regulations,[1] the Petition for Rate Approval pursuant to section 284.123(b)(2) filed by Enterprise Texas Pipeline LLC (Enterprise) on March 13, 2015, in the above referenced docket. Pursuant to the Stipulation and Agreement approved by the Commission in Docket Nos. PR10–14–000 and PR10–14–001,[2] Enterprise filed a new petition for rate approval pursuant to 18 CFR 284.123(b)(2) proposing a new rate applicable to its Natural Gas Policy Act (NGPA) section 311 service. Enterprise elected to use the Commission's new optional notice procedures set forth in section 284.123(g). Enterprise proposes to increase its firm and interruptible transportation services for Rate Zone 1—Legacy Assets and Rate Zone 2—Sherman Extension. Enterprise also proposes to revise its Statement of Operating Conditions (SOC) applicable to its transportation services performed pursuant to NGPA section 311, which it states is updated solely to reflect the new proposed rates. Enterprise states it has not proposed any changes to the operating terms and conditions of its SOC.

2. Commission staff notes that Enterprise has not adequately supported its filing and shown that the proposed rates are fair and equitable. For instance, Enterprise has not provided sufficient support for the discount adjustment used in calculating the billing determinants. In addition, Enterprise has not provided adequate explanation and support for its proposed cost of service, rate base, cost of capital, and cost allocation, among other issues.

3. Commission staff's specific concerns include, in particular, Enterprise's development of its discount adjustment in designing rates. For example, in Zone 2 the proposed rates are significantly higher than the rates Enterprise proposed in its prior rate case, Docket No. PR10–14–000, even though the cost of service for Zone 2 is 20 percent lower and the throughput is 55 percent higher using the same rate design methodology and imputed billing determinants from its prior case. Similarly, using the same methodology to design rates for Zone 1, Enterprise proposes a rate of $0.7636 per Dth, yet the unit cost prior to any discount adjustment is $0.2006 per Dth.

4. Commission staff has concerns that Enterprise has not classified any costs as variable costs when calculating its rates. Enterprise calculated straight-fixed variable rates for Zone 2 but did not classify any costs as variable cost rates. However, since Enterprise included $91.6 million in Account No. 368, Compressor Station Equipment, it follows that there should be variable costs associated with operating and maintaining compressors. Moreover, Account No. 855, Other Fuel and Power for Compressor Stations, typically

[1] 18 CFR 385.216(b) (2014).

[1] 18 CFR 284.123(g)(4)(i) (2014).

[2] *Enterprise Texas Pipeline LLC,* Delegated Letter Order, December 16, 2010.

contains only variable costs. Similarly, for Zone 1, Enterprise did not classify any costs as variable costs, even though Enterprise booked over $509 million to Compressor Station Equipment.

5. Commission staff has concerns regarding the allocation of Administrative and General (A&G) Expenses between Enterprise's two delivery zones. Exhibit H–1 shows that Enterprise allocated only 7.5 percent of A&G Expenses to Zone 2 which seems low considering that over 15 percent of Operating and Maintenance (O&M) Expenses, 15 percent of gross plant and over 14 percent of revenues were derived from Zone 2.

6. Enterprise proposes to include both gathering and storage plant in rate base. This is inconsistent with prior cases, where Enterprise has sometimes included gathering in rate base (see Docket No. PR07–12–000) and also excluded it from rate base (see Docket No. PR10–14–000). Enterprise has provided little to support its proposed treatment of gathering plant. In addition, Commission staff notes that Enterprise has market-based rate authority to provide storage services. Enterprise has not provided sufficient support to include storage plant in rate base for the first time. Further, Enterprise has not included any storage related O&M expenses to operate the plant.

7. Finally, Enterprise has requested a weighted average cost of capital of 10.41 percent without adequate support for either the proposed capital structure or the individual capital cost components.

Dated: May 8, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–11736 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. NJ15–14–000]**

### Oncor Electric Delivery Company LLC; Notice of Filing

Take notice that on April 30, 2015, Oncor Electric Delivery Company LLC submitted its tariff filing per 35.28(e): Oncor TFO Tariff Rate Changes to be effective March 20, 2015.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5:00 p.m. Eastern Time on May 21, 2015.

Dated: May 1, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–11747 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. AC15–117–000]**

### Entergy Gulf States Louisiana, L.L.C., Entergy Louisiana, LLC, Entergy Louisiana Power, LLC; Notice of Filing

Take notice that on April 24, 2015, Entergy Services, Inc. on behalf of its current and prospective public utility affiliates Entergy Gulf States Louisiana, L.L.C. (EGSL), Entergy Louisiana, LLC, (ELL) and Entergy Louisiana Power, LLC (ELP), (collectively, applicants) submitted a request proposing that ELP be allowed to account for the intercompany receivable created on its books following the Business Combination in Account 190, Accumulated Deferred Income Taxes, in a manner consistent with the instructions to FERC's Uniform System of Accounts and guidance provided by the Chief Accountant.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* June 1, 2015.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11774 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2629–000]**

### Village of Morrisville, Vermont; Notice of Authorization for Continued Project Operation

On April 25, 2013 the Village of Morrisville (Vermont), licensee for the Morrisville Hydroelectric Project, filed an Application for a New License

pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. The Morrisville Hydroelectric Project is located on Green River, Elmore Pond Brook, and Lamoille River in Lamoille County, Vermont.

The license for Project No. 2629 was issued for a period ending April 30, 2015. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2629 is issued to the licensee for a period effective May 1, 2015 through April 30, 2016 or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before April 30, 2016, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise. If the project is not subject to section 15 of the FPA, notice is hereby given that the licensee, the Village of Morrisville (Vermont), is authorized to continue operation of the Morrisville Hydroelectric Project, until such time as the Commission acts on its application for a subsequent license.

Dated: May 8, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11692 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10–2290–004.
*Applicants:* Avista Corporation.
*Description:* Notice of Non-Material Change of Status of Avista Corporation.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5039.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–885–000.
*Applicants:* Northern States Power Company, a Minnesota corporation.
*Description:* eTariff filing per 35.19a(b): 2015–5–8_NSP–AIM-Refund Report to be effective N/A.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5132.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–964–002.
*Applicants:* Southwest Power Pool, Inc.
*Description:* Tariff Amendment per 35.17(b): City Utilities of Springfield Formula Rate Amended Filing to be effective 4/1/2015.
*Filed Date:* 5/7/15.
*Accession Number:* 20150507–5202.
*Comments Due:* 5 p.m. ET 5/28/15.

*Docket Numbers:* ER15–1684–000.
*Applicants:* Southern California Edison Company.
*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): Generator Interconnection Agreement to be effective 5/8/2015.
*Filed Date:* 5/7/15.
*Accession Number:* 20150507–5192.
*Comments Due:* 5 p.m. ET 5/28/15.

*Docket Numbers:* ER15–1685–000.
*Applicants:* Town Square Energy East, LLC.
*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Notice of Succession to be effective 4/2/2015.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5000.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–1686–000.
*Applicants:* Rayburn Country Electric Cooperative Inc.
*Description:* Notice of Cancellation of Transmission and Interconnection Agreement of Rayburn Country Electric Cooperative, Inc.
*Filed Date:* 5/7/15.
*Accession Number:* 20150507–5254.
*Comments Due:* 5 p.m. ET 5/28/15.

*Docket Numbers:* ER15–1687–000.
*Applicants:* Blue Cube Operations LLC.
*Description:* Initial rate filing per 35.12 Blue Cube Operations LLC Baseline Tariff Filing to be effective 5/9/2015.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5090.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–1688–000.
*Applicants:* Alabama Power Company.
*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): GCL Lincoln Power SGIA Filing to be effective 4/24/2015.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5103.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–1689–000.
*Applicants:* Midcontinent Independent System Operator, Inc., Dairyland Power Cooperative.
*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–08_DPC Incentive Rate Filing to be effective 7/1/2015.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5114.
*Comments Due:* 5 p.m. ET 5/29/15.

*Docket Numbers:* ER15–1690–000.
*Applicants:* Wisconsin Public Service Corporation.
*Description:* § 205(d) rate filing per 35.13(a)(2)(iii): WPSC's Updated FERC Form 1 References in its Formula Rates to be effective 7/7/2015.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5156.
*Comments Due:* 5 p.m. ET 5/29/15.

Take notice that the Commission received the following qualifying facility filings:

*Docket Numbers:* QF15–381–000.
*Applicants:* KTZ Hydro LLC.
*Description:* Refund Report of KTZ Hydro LLC.
*Filed Date:* 5/8/15.
*Accession Number:* 20150508–5043.
*Comments Due:* 5 p.m. ET 5/8/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 8, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–11734 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP15–296–000]**

### Tallgrass Interstate Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on April 29, 2015, Tallgrass Interstate Gas Transmission, LLC (Tallgrass), 4200 West 115th Street, Suite 350, Leawood, Kansas 66211–2609 filed a prior notice request pursuant to sections 157.205, 157.208 and 157.213 of the Commission's regulations under the Natural Gas Act for authorization to convert the HS–18 observation well in its Huntsman Storage Facility, located in Cheyenne County, Nebraska to an injection and withdrawal well and to construct and operate certain appurtenant pipeline measurement facilities necessary to connect the converted well to the storage facility, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The project will have no impact on the certificated parameters of the Huntsman Storage Facility.

The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this Application should be directed to David Haag, Vice President of Regulatory, Tallgrass Interstate Gas Transmission, LLC, 370 Van Gordon Street, Lakewood, Colorado 80228–1519, by phone at (303) 763–3258.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with he Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11775 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER15–1687–000]**

### Blue Cube Operations LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Blue Cube Operations LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is May 28, 2015.

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 5 copies of the intervention or protest to the Federal Energy Regulatory Commission,

888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) 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 email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 8, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–11735 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER15–1665–000]**

### Greenleaf Power Management LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Greenleaf Power Management LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is June 1, 2015.

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 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic 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 email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11770 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. ID–4482–003; ID–6697–002; ID–7646–000; ID–7647–000]**

### Huskilson, Christopher G.; Aftanas, Stephen D.; Balfour, Scott C.; Bennett, Robert R.; Notice of Filing

Take notice that on May 8, 2015, Christopher G. Huskilson, Stephen D. Aftanas, Scott C. Balfour, and Robert R. Bennett submitted for filing, an application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act (FPA), 16 U.S.C. 825d(b), Part 45.8 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic 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 email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5:00 p.m. Eastern Time on May 29, 2015.

Dated: May 11, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11771 Filed 5–14–15; 8:45 am]

**BILLING CODE 6717–01–P**

---

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 14215–002]**

### Spartanburg Water System; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 3, 2015, Spartanburg Water System filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Fingerville Project to be located at the existing Fingerville Dam, on the North Pacolet River, near the town of Fingerville, Spartanburg County, South Carolina. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit

term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of: (1) An existing 11.3-foot-high, 171-foot-long wooden dam, owned by Spartanburg; (2) a reservoir with a surface area of 11.69 acres; (3) a 130-foot-long headrace channel; (4) a powerhouse containing one generating unit with a total capacity of 150.0 kilowatts (kW); (4) a tailrace; and (5) a 450-foot-long, 12 kilo-volt (KV) transmission line. The project would have an estimated average annual generation of 770.0 megawatt-hours (MWh).

*Applicant Contact:* Ms. Sue Schneider, Spartanburg Water System, 200 Commerce Street, P.O. Box 251, Spartanburg, SC 29304, (864) 580–5642.

*FERC Contact:* Michael Spencer; phone: (202) 502–6093.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14215–002.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number (P–14215) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 8, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11693 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 14676–000]**

### Mid-Atlantic Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 21, 2015, Mid-Atlantic Hydro, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Milford Hydroelectric Project (Milford Project) to be located on Republic River, near Junction City, Geary County, Kansas. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A 30-foot-long, 50-foot-wide, 30-foot-high bifurcation structure connecting to the end of an existing 615.5-foot-long, 21-foot-wide concrete horseshoe-shaped conduit serving as the outlet for the Milford Dam Reservoir; (2) a 7-foot-diameter penstock extending from the bifurcation to the powerhouse; (3) a 50-foot-long, 50-foot-wide, 30-foot-high concrete powerhouse located downstream of the existing Milford Dam and adjacent to the south abutment, containing two 1.5 megawatts Francis turbine generating units; (4) a 75-foot-long, 50-foot-wide concrete tailrace directing flows from the powerhouse back to the existing stilling basin; (5) a 4,440-foot-long, 12.7-kilovolt transmission line delivering the project power to a distribution line belonging to the local electric cooperative; (6) a 40-foot-long, 40-foot-wide switchyard containing a three-phase step-up transformer, protective equipment, and metering; (7) appurtenant facilities. The estimated annual generation of the Milford Project would be 15,000 megawatt-hours annually.

*Applicant Contact:* Mr. Juan Kimble, President, Mid-Atlantic Hydro, LLC, 5425 Wisconsin Avenue, Suite 600, Chevy Chase, MD 20815; phone: (301) 718–4496.

*FERC Contact:* Sergiu Serban; phone: (202) 502–6211; email *sergiu.serban@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14676–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14676) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 8, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–11694 Filed 5–14–15; 8:45 am]

BILLING CODE 6717–01–P

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OAR–2008–0707; FRL—9927–78–OAR]**

### Proposed Information Collection Request; Comment Request; Data Reporting Requirements for State and Local Vehicle Emission Inspection and Maintenance (I/M) Programs

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency is planning to submit an

information collection request (ICR), ''Data Reporting Requirements for State and Local Vehicle Emission Inspection and Maintenance (I/M) Programs'' (EPA ICR No.1613.05, OMB Control No. 2060–0252) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through November 30, 2015. 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.

**DATES:** Comments must be submitted on or before July 14, 2015.

**ADDRESSES:** Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2008–0707, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Dave Sosnowski, Transportation and Climate Division, State Measures and Transportation Planning Center, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number:734–214–4823; fax number: 734–214–4052; email address: *sosnowski.dave@epa.gov*.

**SUPPLEMENTARY INFORMATION:** Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it 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 will have practical utility; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* Clean Air Act section 182 and EPA's regulations (40 CFR part 51, subpart S) establish the requirements for state and local I/M programs that are included in state implementation plans (SIPs). To provide general oversight and support to these programs, the U.S. Environmental Protection Agency requires that state agencies with basic and enhanced I/M programs collect two varieties of reports for submission to EPA:

- An annual report providing general program operating data and summary statistics, addressing the program's current design and coverage, a summary of testing data, enforcement program efforts, quality assurance and quality control efforts, and other miscellaneous information allowing for an assessment of the program's relative effectiveness; and
- A biennial report on any changes to the program over the two-year period and the impact of such changes, including any weaknesses discovered and corrections made or planned.

General program effectiveness is determined by the degree to which a program misses, meets, or exceeds the emission reductions committed to in the state's approved SIP, which, in turn, must meet or exceed the minimum emission reductions expected from the relevant performance standard, as promulgated under EPA's revisions to 40 CFR, part 51, subpart S, in response to requirements established in section 182 of the Clean Air Act. This information is used by EPA to determine a program's progress toward meeting requirements under 40 CFR, part 51, subpart S, and to provide background information in support of program evaluations. Additional information regarding the current renewal of this ICR as well as previous renewals can be found in Docket ID No. EPA–HQ–OAR–2008–0707.

*Form Numbers:* None.

*Respondents/affected entities:* state I/M program managers.

*Respondent's obligation to respond:* mandatory (40 CFR 51.366).

*Estimated number of respondents:* 28 state air quality agencies (total).

*Frequency of response:* annual and biennial.

*Total estimated burden:* 2,408 hours (per year). Burden is defined at 5 CFR 1320.03(b)

*Total estimated cost:* $147,462 (per year), includes $0 annualized capital or operation & maintenance costs.

*Changes in Estimates:* There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Dated: May 6, 2015.

**Karl Simon,**

*Director, Transportation and Climate Division, Office of Transportation and Air Quality.*

[FR Doc. 2015–11802 Filed 5–14–15; 8:45 am]

**BILLING CODE 6560–50–P**

---

## ENVIRONMENTAL PROTECTION AGENCY

**[ER–FRL–9020–9]**

## Environmental Impact Statements; Notice of Availability

*Responsible Agency:* Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 05/04/2015 through 05/08/2015

Pursuant to 40 CFR 1506.9.

### Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search*.

*EIS No. 20150126, Final, NRC, OH,* Generic-License Renewal of Nuclear Plants Regarding Davis-Besse Nuclear Power Station, Review Period Ends: 06/15/2015, Contact: Elaine Keegan 301–415–8517.

*EIS No. 20150127, Draft, FHWA, LA,* US 61 to I–10, Saint John the Baptist

Parish, Reserve to I–10 Connector, Comment Period Ends: 07/01/2015, Contact: Carl M. Highsmith 225–757–7615.

*EIS No. 20150128, Draft, USFWS, CO,* Rocky Mountain Arsenal National Wildlife Refuge Draft Comprehensive Conservation Plan, Comment Period Ends: 06/29/2015, Contact: Bernardo Garza (303) 236–4377.

*EIS No. 20150129, Draft, BIA, NV,* Aiya Solar Project, Comment Period Ends: 06/29/2015, Contact: Chip Lewis 602–379–6782.

*EIS No. 20150130, Final, BR, WA,* Cle Elum Pool Raise Project—A Component of the Yakima River Basin Integrated Water Resource Management Plan, Review Period Ends: 06/15/2015, Contact: Candace McKinley 509–575–5848 ext. 232.

**Amended Notices**

*EIS No. 20150123, Draft, NPS, ID,* City of Rocks National Reserve Draft General Management Plan, Comment Period Ends: 07/07/2015, Contact: Wallace Keck 208–824–5911. Revision to FR Notice Published 05/08/2015; Correction to Comment Period to End 07/07/2015.

*EIS No. 20150088, Draft, USMC, 00,* Commonwealth of the Northern Mariana Islands (CJMT) Joint Military Training, Comment Period Ends: 08/03/2015, Contact: Lori Robertson 808–472–1409. Revision to FR Notice Published 04/03/2015; Extending Comment Period from 06/02/2015 to 08/03/2015.

Dated: May 13, 2015.

**Dawn Roberts,**

*Management Analyst, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2015–11948 Filed 5–14–15; 8:45 am]

BILLING CODE 6560–50–P

## EXPORT-IMPORT BANK OF THE UNITED STATES

**[Public Notice 2015–0013]**

### Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088970XX

**AGENCY:** Export-Import Bank of the United States.

**ACTION:** Notice.

**SUMMARY:** This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction. Comments received will be made available to the public.

**DATES:** Comments must be received on or before June 9, 2015 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

**ADDRESSES:** Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2015–0013 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2015–0013 on any attached document.

*Reference:* AP088970XX.

**Purpose and Use**

*Brief description of the purpose of the transaction:*

To support the export of U.S.-manufactured goods and services to be used in Pemex oil and gas projects.

*Brief non-proprietary description of the anticipated use of the items being exported:*

To be used for Pemex's on- and off-shore oil and gas exploration and production areas.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

**Parties**

*Principal Supplier:* Diamond Offshore Services Co.

*Obligor:* Petroleos Mexicanos.

*Guarantor(s):* Pemex Exploracion y Produccion; Pemex Refinacion; Pemex Gas y Petroquimica Basica.

**Description of Items Being Exported**

Drilling rigs, platform rentals, compressors, oil field services and related equipment.

*Information on Decision:* Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

*Confidential Information:* Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

**Lloyd Ellis,**

*Program Specialist, Office of the General Counsel.*

[FR Doc. 2015–11790 Filed 5–14–15; 8:45 am]

BILLING CODE 6690–01–P

## EXPORT-IMPORT BANK OF THE UNITED STATES

**[Public Notice 2015–0012]**

### Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088969XX

**AGENCY:** Export-Import Bank of the United States.

**ACTION:** Notice.

**SUMMARY:** This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction. Comments received will be made available to the public.

**DATES:** Comments must be received on or before June 9, 2015 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

**ADDRESSES:** Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2015–0012 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2015–0012 on any attached document.

*Reference:* AP088969XX.

**Purpose and Use**

*Brief description of the purpose of the transaction:*

To support the export of U.S. small business manufactured goods and services to be used in Pemex oil and gas projects.

*Brief non-proprietary description of the anticipated use of the items being exported:*

To be used for Pemex's on- and off-shore oil and gas exploration and production areas.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

**Parties**

*Principal Supplier:* Northpoint Drilling Systems.

*Obligor:* Petroleos Mexicanos.

*Guarantor(s):* Pemex Exploracion y Produccion; Pemex Refinacion; Pemex Gas y Petroquimica Basica.

**Description of Items Being Exported**

Drilling rigs, platform rentals, compressors, oil field services and related equipment.

*Information on Decision:* Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/*.

*Confidential Information:* Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

**Lloyd Ellis,**

*Program Specialist, Office of the General Counsel.*

[FR Doc. 2015–11789 Filed 5–14–15; 8:45 am]

**BILLING CODE 6690–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

**[DA 15–535, DA 15–324, DA 14–1806]**

## Consumer Advisory Committee

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission announces renewal of charter, appointment of members and designation of chairperson of its Consumer Advisory Committee (Committee). The Commission further announces the Committee's next meeting date, time, and agenda. The mission of the Committee is to make recommendations to the Commission regarding consumer issues within the jurisdiction of the Commission and to facilitate the participation of consumers (including underserved populations, such as Native Americans, persons living in rural areas, older persons, people with disabilities, and persons for whom English is not their primary language) in proceedings before the Commission.

**DATES:** The meeting of the Committee will take place on Friday June 12, 2015, 9:00 a.m. to 4:00 p.m., at the Commission's Headquarters Building, Commission Meeting Room TW–C305.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Scott Marshall, Consumer and Governmental Affairs Bureau, (202) 418–2809 (voice or Relay), or email *Scott.Marshall@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's documents [DA 15–535] dated and released May 5, 2015, [DA 15–324] dated and released March 17, 2015 and [DA–14–1806] dated and released December 10, 2014.

By Public Notice [DA 14–1806] dated and released December 10, 2014, the Commission announced the renewal of the Committee for an eighth two year term, and solicited applications for membership thereon. This renewal was necessary and in the public interest. Numerous applications were received through January 20, 2015, at which time the period for receipt of applications closed.

On March 12, 2015, the Commission released a Report and Order on Remand, Declaratory Ruling, and Order in the Matter of Protecting and Promoting the Open Internet (NG Docket No. 1428), adopted on February 26, 2015. The Commission's Open Internet Order directed the CAC to ''formulate and submit to the Commission a proposed [Open Internet enhanced transparency rule] disclosure format, based on input from a broad range of stakeholders, within six months of the time that its new membership is reconstituted, but, in any event, no later than October 31, 2015.'' This disclosure format must be accessible to persons with disabilities. The Commission stated its expectation that the CAC ''will consider whether to propose the same or different formats for fixed and mobile broadband providers.'' Additionally, the Commission expects the CAC to consider ''whether and how a standard format for mobile broadband providers will allow providers to continue to differentiate their services competitively, as well as how mobile broadband providers can effectively disclose commercial terms to consumers regarding myriad plans in a manner that is not administratively burdensome.'' This recommendation may serve as a potential safe harbor for broadband providers seeking to meet the Commission's Open Internet transparency requirements.

To assist the Committee in responding to this charge and in furtherance of the Committee's other responsibilities, the Commission, by public Notice [DA 15–324], dated and released March 17, 2015 announced a second solicitation of applications for membership on the Committee. Several additional applications were received through April 1, 2015, at which time the period for receipt of second round applications closed.

The Committee will operate in accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2 (1988). Each meeting of the Committee will be open to the public. A notice of each meeting will be published in the **Federal Register** at least fifteen (15) days in advance of the meeting. Records will be maintained of each meeting and made available for public inspection.

During the Committee's eighth term, it is anticipated that the Committee will meet in Washington, DC for a minimum of two (2) one-day plenary meetings per year. In addition, as needed, working groups or subcommittees will be established to facilitate the Committee's work between meetings of the full Committee. Meetings will be fully accessible to individuals with disabilities.

Members must be willing to commit to a two (2) year term of service, and should be willing and able to attend a minimum of two (2) one-day plenary committee meetings per year in Washington, DC Committee members are also expected to participate in deliberations of at least one (1) working group or subcommittee.

**Appointment of Members and Chairperson**

By Public Notice [DA 15–535] dated and released May 5, 2015, the Commission announced the appointment of thirty-seven (37 members of the Committee. Of these, twenty-one (21) represent general consumer organizations/academia, two (2) represent disability organizations, eight (8) represent industry, four (4) represent regulators, one (1) represents seniors, and one (1) represents unions. The Committee's membership is designed to be representative of the Commission's many constituencies, and the diversity of the selected members will provide a balanced point of view as

required by the Federal Advisory Committee Act. In addition, Chairman Wheeler reappoints Debra R. Berlyn representing the National Consumers League as Chairperson of the Committee. All appointments and reappointments are effective immediately and shall terminate October 21, 2016, or when the Committee is terminated, whichever is earlier.

The Committee's roster by organization name and primary representative is as follows:

(1) AARP—Christopher Baker
(2) American Consumer Institute—Stephen Pociask
(3) American Foundation for the Blind—Paul W. Schroeder
(4) American Indian Policy Institute, Arizona State University—Dr. Traci Morris
(5) Americans for Tax Reform—Katie McAuliffe
(6)Appalachian Regional Commission—Mark Defalco
(7) Benton Foundation—Amina Fazlullah
(8) California Western School of Law, New Media Rights—Art Neill
(9) Call For Action—Shirley Rooker
(10) Center for Democracy and Technology—Chris Calabrese
(11) Center for Media Justice/MAGNET—Hannah Sassaman
(12) CenturyLink—Melissa Newman
(13) Common Cause—Todd O'Boyle
(14) Communication Workers of America—Debbie Goldman
(15) Consumer Action—Ken McEldowney
(16) Consumer Electronics Association—Julie Kearney
(17) Consumer Federation of America—Irene E. Leech
(18) Deaf and Hard of Hearing Consumer Advocacy Network—Claude Stout
(19) Digital Policy Institute—Barry D. Umansky
(20) Free Press—Lauren Wilson
(21) Google, Inc.—Eve Anderson
(22) International Center for Law and Economics—Geoffrey A. Manne
(23) Massachusetts Department of Telecommunications and Cable—Joslyn Day
(24) National Association of Broadcasters—Ann West Bobeck
(25) National Association of Counties—Yejin Jang
(26) National Association of State Utility Consumer Advocates—Kenneth Mallory
(27) National Association of Telecommunications Officers and Administrators—Mitsuko R. Herrera
(28) National Cable and Telecommunications Association—Stephanie Podey
(29) National Consumer Law Center—Olivia Wein
(30) National Consumers League—Debra R. Berlyn (Chairperson)
(31) National Hispanic Media Coalition—Michael Scurato
(32) New America Foundation, Open Technology Institute—Laura Moy
(33) Program on Information Justice and Intellectual Property, Washington College of Law, American University—Victoria F. Phillips
(34) T-Mobile—Luisa L. Lancetti
(35) TRAIL—Christina Gagnier
(36) Verizon Communications, Inc.—Ann Berkowitz
(37) Wireless Internet Service Provider Association—Alex Phillips

**Meeting Date, Time & Agenda**

The first meeting of the Committee under its renewed charter will take place on June 12, 2015, from 9:00 a.m. to 4:00 p.m. at the Commission's headquarters building, Commission Meeting Room TW–C305, 445 12th Street SW., Washington, DC 20554.

At its June 12, 2015 meeting, the Committee will consider administrative and procedural matters relating to its functions and will also discuss development of a proposed Open Internet enhanced transparency rule disclosure format, as directed in the Commission's Open Internet Order referenced above.

The Committee may receive briefings from commission staff and/or outside speakers on issues of interest to the Committee. A limited amount of time will be available on the agenda for comments from the public. If time permits, the public may ask questions of presenters via the email address *livequestions@fcc.gov* or via Twitter using the hashtag #fcclive. In addition, the public may also follow the meeting on Twitter @fcc or via the Commission's Facebook page at *www.facebook.com/fcc.* Alternatively, members of the public may send written comments to: Scott Marshall, Designated Federal Officer of the Committee at the address provided above.

The meeting is open to the public and the site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, assistive listening devices, and Braille copies of the agenda and committee roster will be provided on site. Meetings of the Committee are also broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live/.*

Other reasonable accommodations for people with disabilities are available upon request. The request should include a detailed description of the accommodation needed and contact information. Please provide as much advance notice as possible; last minute requests will be accepted, but may not be possible to fill. To request an accommodation, send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Federal Communications Commission.

**Kris Anne Monteith,**

*Acting Chief, Consumer and Governmental Affairs Bureau.*

[FR Doc. 2015–11859 Filed 5–14–15; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 11, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First Illinois Corporation and HPB Holdings, Inc.,* both in Decatur, Illinois; to become bank holding companies upon the conversion of Hickory Point

Bank and Trust, FSB, Decatur, Illinois, from a federal savings bank to a commercial bank.

Board of Governors of the Federal Reserve System, May 12, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2015–11757 Filed 5–14–15; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL TRADE COMMISSION

**[File No. 141–0235]**

## ZF Friedrichshafen AG and TRW Automotive Holdings Corp; Analysis of Proposed Consent Order To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before June 5, 2015.

**ADDRESSES:** Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/zftrwautomativeconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''ZF Friedrichshafen AG's and TRW Automotive Holdings Corp.—Consent Agreement; File No. 141–0235'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/zftrwautomativeconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''ZF Friedrichshafen AG's and TRW Automotive Holdings Corp.—Consent Agreement; File No. 141–0235'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Stephen Antonio, Bureau of Competition, (202–326–2536), 600 Pennsylvania Avenue NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 5, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 5, 2015. Write ''ZF Friedrichshafen AG's and TRW Automotive Holdings Corp.—Consent Agreement; File No. 141–0235'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/zftrwautomativeconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''ZF Friedrichshafen AG's and TRW Automotive Holdings Corp.—Consent Agreement; File No. 141–0235'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 5, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

## Analysis of Agreement Containing Consent Order To Aid Public Comment

### Introduction

The Federal Trade Commission (''Commission'') has accepted from ZF Friedrichshafen AG (''ZF'') and TRW Automotive Holdings Corp. (''TRW''), subject to final approval, an Agreement Containing Consent Order (''Consent Agreement'') designed to remedy the anticompetitive effects resulting from ZF's proposed acquisition of TRW.

Pursuant to an Agreement and Plan of Merger dated September 15, 2014, the parties agreed that ZF would acquire TRW for $105.60 per share in an all-cash deal valued at approximately $12.4 billion (''the Acquisition''). The proposed Acquisition would result in a duopoly in the heavy vehicle tie rod market. The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the market for heavy vehicle tie rods in North America.

Under the terms of the proposed Decision and Order (''Order'') contained in the Consent Agreement, the parties are required to divest TRW's Linkage and Suspension Business in a manner, and to an acquirer, that meets Commission approval. The divestiture package includes five manufacturing facilities in North America and Europe, along with related assets including intellectual property. The acquirer also has the option to enter into transitional services and supply agreements. The Consent Agreement provides an acquirer with everything needed to compete effectively in the North American heavy vehicle tie rod market. The parties must complete the divestiture within six months of executing the Consent Agreement.

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

### The Parties

Headquartered in Friedrichshafen, Germany, ZF is a privately held global automotive and industrial products manufacturer. ZF makes light and heavy vehicle components for the powertrain, chassis, and driveline. ZF designs, manufacturers, and sells heavy vehicle tie rods, amongst several other products, in its chassis division.

Headquartered in Livonia, Michigan, TRW sells chassis systems, electronic systems, passive occupant safety systems, and other automotive components. Like ZF, TRW designs, manufactures, and sells heavy vehicle tie rods.

### The Relevant Product and Market Structure

The relevant line of commerce in which to analyze the effects of the Acquisition is heavy vehicle tie rods. A heavy vehicle is generally defined as one that weighs six tons or more, and a tie rod is a rigid connecter that links a vehicle's individual wheels with the steering control mechanism. Customers and other market participants did not identify any substitutes for heavy vehicle tie rods.

North America is the relevant geographic market in which to analyze the effects of the Acquisition on the heavy vehicle tie rod market. The size and weight of heavy vehicle tie rods generally make it uneconomical to ship them long distances. Customers interviewed primarily consider manufacturers in North America, and have found more distant firms uncompetitive for reasons including: (1) Price; (2) logistics; and (3) quality. Therefore, North America is the relevant geographic market.

The market for heavy vehicle tie rods in North America is highly concentrated. It is served primarily by ZF, TRW, and USK Internacional S.A. DE C.V. (''Urresko''). These three firms have a share of nearly 99% of the market based on unit sales. The merger would reduce the number of competitors from three to two, and increase the Herfindahl-Hirschman Index from 4,218 to 5,046, an increase of 828.

### Entry

Entry into the North American heavy vehicle tie rod market is not likely to deter or counteract any anticompetitive effects of the proposed Acquisition. Entry is unlikely in light of the relatively small market size, strong position of incumbents, high capital costs, switching costs, and knowledge barriers that exist. The parties did not identify any likely entrants, and those firms best situated for entry—manufacturers of related heavy vehicle components—expressed no interest in entering the North American heavy vehicle tie rod market.

### Effects of the Acquisition

The proposed Acquisition would increase the likelihood of coordinated interaction among the remaining competitors in the North American heavy vehicle tie rod market. The combined company would have only one remaining significant competitor in North America, Urresko. Reducing the number of competitors from three to two would eliminate much uncertainty and make it easier for the remaining firms to reach agreement on terms of coordination, whether the coordination focuses on customer allocation, price, or some other aspect of competition.

Additionally, the proposed Acquisition would eliminate direct competition between ZF and TRW, resulting in the increased probability that customers would pay higher prices for heavy vehicle tie rods. In the past, customers have been able to use competition between ZF and TRW to obtain better prices by obtaining competing bids. Customers have also switched between ZF and TRW. That competition would be lost absent the merger.

### The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by ZF's proposed acquisition of TRW by requiring the parties to divest TRW's North American and European Linkage and Suspension Business (''the L&S Business''). The proposed divestiture includes everything needed for an acquirer to compete effectively in the North American market for heavy vehicle tie rods, and also includes additional products that ensure the business will be viable. Given the robust nature of the divested business, the Commission is confident that a post-order divestiture is sufficient to protect its interest in restoring competition.

Pursuant to the Order, the parties are required, no later than six months from execution of the Consent Agreement, to divest the L&S Business to a Commission-approved acquirer. That business consists of both heavy and light vehicle components, and includes—in addition to tie rods—control arms, ball joints, stabilizer links, conventional steering linkages, drag links, V-links, radius rods, and I-shafts. The divestiture buyer will receive all rights and assets relating to the L&S Business, including five TRW manufacturing facilities, Portland (U.S.), Tillsonburg-Plant 2 (Canada), St. Catharines (Canada), Dacice (Czech Republic), and Krefeld-Gellep (Germany), as well as leased space previously occupied by L&S research

and development at TRW's Dusseldorf Tech Center. The divested assets also include intellectual property rights as well as all books, records, and confidential business information related to the L&S Business.

To ensure that the divestiture is successful, the Order requires the parties to provide transition services such as logistical and administrative support at the option of the acquirer. Moreover, the acquirer will have the option to enter into a transition supply agreement with the parties for key manufacturing inputs necessary to perform existing customer contracts. The Consent Agreement also includes other standard terms designed to ensure the viability of the divestiture, including requirements that the parties assist the acquirer in hiring the existing work force of the business, and refrain from soliciting those employees for up to two years.

Given the robustness of the divested business and the protections contained in the Order, the Commission is confident that a post-order divestiture will be sufficient to preserve competition. The L&S Business has been run largely as a standalone business within TRW, and potential buyers have confirmed that the divested assets include everything necessary to compete effectively as a viable business. Similarly, potential customers have confirmed that an acquirer of the L&S Business would be a workable option as a supplier.

To ensure compliance with the Order, the Commission will appoint an Interim Monitor to oversee ZF's and TRW's performance of their obligations pursuant to the Consent Agreement, and to keep the Commission informed about the status of the divestiture. The Order also allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture if the parties fail to divest within the required timeframe. Lastly, the Consent Agreement contains standard reporting requirements and terminates in ten years.

The Commission has also issued an Order to Hold Separate and Maintain Assets to protect the assets until they are divested. During the hold separate period, the parties must fund the business' operations, including capital projects, according to existing plans. To ensure compliance with the Hold Separate Order, a Commission-approved Hold Separate Monitor will oversee the L&S Business during the interim period.

## Opportunity for Public Comment

The purpose of this analysis is to facilitate public comment on the Consent Agreement to aid the Commission in determining whether it should make the Consent Agreement final. This analysis is not an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.

By direction of the Commission, Commissioner Wright dissenting.

**Donald S. Clark,**

*Secretary.*

## Statement of the Federal Trade Commission

## In the Matter of ZF Friedrichshafen AG and TRW Automotive Holdings Corp.

The Commission has issued a proposed complaint and consent order to address narrow competitive concerns associated with ZF Friedrichshafen AG's proposed $12.4 billion acquisition of TRW Automotive Holdings Corp.[1] Specifically, we have reason to believe that this proposed acquisition is likely to substantially reduce competition in the manufacture and sale of heavy vehicle tie rods in North America. The proposed remedy, which involves a divestiture of TRW's linkage and suspension business in North America and Europe, addresses our competitive concerns and will bolster the viability of the divested business in the hands of a buyer, without eliminating efficiencies that otherwise might arise from the combination of the two companies.

ZF and TRW are global automotive parts manufacturers. Both companies manufacture and sell a wide variety of components for discrete systems within a motor vehicle such as the chassis, powertrain, and suspension systems. They each have production facilities located throughout the United States, Canada, and Mexico.

The proposed transaction will create the second-largest global auto parts supplier. Our competitive concerns arise from a limited aspect of the proposed combination, namely, its likely effect in the market for the manufacture and sale of heavy vehicle tie rods for customers in North America. Tie rods are part of a motor vehicle's steering and linkage system; they are rigid connectors that link the wheels to the vehicle's steering control mechanism. To perform their intended function within the linkage systems of vehicles weighing six tons or more, these tie rods have to be large (approximately three to six feet long) and heavy (weighing approximately 50 pounds). This means that tie rods designed for light vehicles are not practical substitutes since they would be too small and light and therefore not as strong structurally. At the same time, tie rods designed for much heavier, industrial vehicles (like mining vehicles weighing hundreds of tons) would not be substitutes either.

Because of their weight, it is not economical to ship heavy vehicle tie rods over long distances. For this reason, North American customers primarily consider manufacturers with production facilities in the United States, Canada, and Mexico and generally do not regard suppliers outside of North America as viable options for reasons of price, logistics, and quality. As a result, ZF and TRW, together with a Mexican firm, USK Internacional, S.A. de C.V. (''Urresko''), account for virtually all (99%) of the sales of heavy vehicle tie rods in North America. We estimate the market shares of ZF, TRW, and Urresko to be 23%, 18%, and 58%, respectively. Fringe competitors hold the remaining 1% market share.

The parties' proposed combination will therefore reduce the number of significant competitors in the relevant market from three to two and substantially increase concentration in an already highly concentrated market.[2] Based on this increase in concentration and current market conditions, we believe the transaction is likely to produce substantial anticompetitive effects in the relevant market, in particular, by increasing the potential for coordination. Furthermore, there is unlikely to be any entry that would alleviate our competitive concerns. The small market size, the strong position of the incumbents, switching costs, and capital and knowledge barriers, among other factors, would more than likely deter North American manufacturers of related automotive parts—the most logical candidates for entry—from expanding their product offerings to include heavy vehicle tie rods. Consequently, we have reason to believe that the proposed combination would substantially lessen competition in the relevant market and harm customers and consumers, thereby violating Section 7 of the Clayton Act.

In light of the foregoing, we respectfully disagree with Commissioner Wright's assertions that we lack a ''credible basis'' on which to conclude that the merger may enhance

[1] This statement reflects the views of Chairwoman Ramirez and Commissioners Brill, Ohlhausen, and McSweeny.

[2] The proposed transaction would increase the Herfindahl-Hirschman Index (''HHI'') in the relevant market from 4,218 to 5,046. The threshold at which a market is considered ''highly concentrated'' under the Merger Guidelines is 2,500. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 5.3 (2010).

the risk of coordination and that our action is otherwise inconsistent with the 2010 Horizontal Merger Guidelines.[3] Under the 2010 Guidelines, substantial increases in concentration caused by a merger rightly continue to play an important role in our merger analysis.[4] They do so for the simple reason that highly concentrated markets are more conducive to anticompetitive outcomes than less concentrated markets.[5] Accordingly, the lens we apply to the evidence in a merger that reduces the number of firms in a market to three or two is, and should be, different than the lens we apply to a merger that reduces the number of firms to seven or six. Where, as here, a proposed merger significantly increases concentration in an already highly concentrated market, a presumption of competitive harm is justified under both the Guidelines and well-established case law.[6]

Despite Commissioner Wright's insistence to the contrary, our inquiry extended beyond consideration of market concentration and application of the Guidelines presumption of competitive harm. We also examined the transaction's likely anticompetitive effects, and are satisfied that there is sufficient evidence to support the issuance of our complaint and proposed consent order.[7] As noted above, we are particularly concerned that the transaction is likely to enhance the potential for coordination.[8] As set forth in the Guidelines, the Commission is likely to challenge a merger under a coordinated effects theory if: ''(1) The merger would significantly increase concentration and lead to a moderately or highly concentrated market; (2) that market shows signs of vulnerability to coordinated conduct [ ]; and (3) the [Commission has] a credible basis on which to conclude that the merger may enhance that vulnerability.'' [9] We have reason to believe that all three factors are satisfied here.[10]

First, as noted above, the proposed transaction results in a highly concentrated relevant market.[11] Second, the market is susceptible to coordinated conduct, as evidenced by several recent cases of collusion in the auto parts industry.[12] Third, by reducing the number of significant competitors to only two, the merger would decrease the impediments to reaching common terms of coordination and make it easier to monitor compliance with, and retaliate against potential deviation from, a coordinated scheme. Specifically, as remaining duopolists with nearly equal shares (41% and 58%, respectively), the combined firm and Urresko would have greater incentives to take advantage of a market with relatively few customers that purchase homogeneous products through individual purchase orders rather than long-term supply contracts. They would also find it easier to divide customers and monitor their allocations.

Our concern that the merger may enhance the relevant market's vulnerability to coordination is backed by the well-accepted view that markets with only two or three firms are more conducive to anticompetitive outcomes than markets with four or more firms.[13] The proposed merger would eliminate a third competitor and create greater symmetry between the two remaining firms.

Additionally, there is no evidence that fringe competitors, which have higher prices, or new entrants, which are unlikely to materialize, could disrupt any coordination between the combined firm and Urresko. For these reasons, we have ample basis to conclude that the merger may enhance the vulnerability to coordinated effects that already exists in the relevant market.[14]

As we noted above, the parties have chosen to address our limited competitive concerns in the heavy vehicle tie rods market through a proposal to divest TRW's linkage and suspension business in North America and Europe. This allows the parties to address our competition concerns, as well as those of the European Commission. The EC has already

[3] Dissenting Statement of Commissioner Joshua D. Wright at 3–4.

[4] *See* Carl Shapiro, *The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years,* 77 Antitrust L.J. 701 (2010) (''Thus, like the fox, the 2010 Guidelines embrace multiple methods. But this certainly does *not* mean they reject the use of market concentration to predict competitive effects, as can be seen in Sections 2.1.3 and 5.''). As Commissioner Wright acknowledges, ''The predictive power of market share and market concentration data is informed by economic theory and available empirical evidence.'' Wright Dissent at 7.

[5] *See, e.g.,* Steven C. Salop, *The Evolution and Vitality of Merger Presumptions: A Decision-Theoretic Approach* 11 (Georgetown Law Faculty Publications and Other Works, Working Paper No. 1304, 2014), *available at http://scholarship.law.georgetown.edu/facpub/1304* (''[V]arious theories of oligopoly conduct—both static and dynamic models of firm interaction—are consistent with the view that competition with fewer significant firms on average is associated with higher prices. . . . Accordingly, a horizontal merger reducing the number of rivals from four to three, or three to two, would be more likely to raise competitive concerns than one reducing the number from ten to nine, *ceteris paribus.*''); Steffen Huck, et al., *Two Are Few and Four Are Many: Number Effects from Experimental Oligopolies,* 53 J. Econ. Behavior & Org. 435, 443 (2004) (testing the frequency of collusive outcomes in Cournot oligopolies and finding ''clear evidence that there is a qualitative difference between two and four or more firms''); Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets,* 99 J. Pol. Econ. 977, 1006 (1991) (finding, in a study of tire prices, that ''[m]arkets with three or more dealers have lower prices than monopolists or duopolists,'' and noting that, ''while prices level off between three and five dealers, they are higher than unconcentrated market prices'').

[6] *See* Merger Guidelines § 2.1.3 (''Mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power, but this presumption can be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power.''); *Chicago Bridge & Iron Co., N.V.* v. *FTC,* 534 F.3d 410, 423 (5th Cir. 2008) (''Typically, the Government establishes a *prima facie* case by showing that the transaction in question will significantly increase market concentration, thereby creating a presumption that the transaction is likely to substantially lessen competition.''); *FTC* v. *H.J. Heinz Co.,* 246 F.3d 708, 716 (D.C. Cir. 2001) (merger to duopoly creates a rebuttable presumption of anticompetitive harm through direct or tacit coordination).

[7] The investigation in this matter did not proceed to a full phase because the parties proposed a remedy soon after second requests had been issued. Consequently, the quantum of evidence is not the same as if the agency had completed a full-phase investigation. But that does not mean, as Commissioner Wright suggests, that we are lowering our reason-to-believe standard when a remedy is proposed during the course of an investigation. Wright Dissent at 9. We believe our complaint is well supported and meets the same reason-to-believe standard we always apply. We simply do not think it would have been appropriate to subject the parties to the added expense and delay of a full-phase investigation. It would not have been a good use of Commission resources either.

[8] Although coordinated effects is the primary basis upon which we found reason to believe that the proposed transaction violates Section 7 of the Clayton Act, we also found evidence of unilateral effects, namely, that in the past, customers have solicited competing bids from ZF and TRW to obtain better prices, and have switched between ZF and TRW as their preferred supplier.

[9] Merger Guidelines § 7.1.

[10] 15 U.S.C. 45(b) (2013).

[11] *See* Shapiro, *supra* note 4, at 708 (''In particular, as the revised Guidelines explain, the Agencies place considerable weight on HHI measures in cases involving coordinated effects.'').

[12] Among the Antitrust Division's recent prosecutions of companies and individuals in the automotive parts industry for price-fixing and bid-rigging is an indictment involving TRW in an alleged conspiracy for seat belts, air bags, and steering wheels. *See* Plea Agmt., *United States* v. *TRW Deutschland Holding GMBH,* Crim. No. 12–20491 (E.D. Mich. Sept. 25, 2012), *available at http://www.justice.gov/atr/cases/f287600/287657.pdf. See generally* Merger Guidelines § 7.2 (''Previous collusion or attempted collusion in another product market may also be given substantial weight if the salient characteristics of that other market at the time of the collusion are closely comparable to those in the relevant market.'').

[13] *See* Salop; Huck et al.; Bresnahan & Reiss, *supra* note 5.

[14] *See* Merger Guidelines § 7.1 (recognizing that ''the risk that a merger will induce adverse coordinated effects may not be susceptible to quantification or detailed proof''). The Guidelines contemplate that the third factor can be satisfied in several ways; as Commissioner Wright himself notes, an acquisition of a maverick firm is but ''one illustrative example of the type of evidence that would satisfy this third condition.'' Wright Dissent at 3.

accepted the proposed settlement and ordered the divestiture of the European assets.[15] Furthermore, there is no evidence that the divestiture of TRW's linkage and suspension business would eliminate any efficiencies that otherwise might result from the parties' proposed combination.

In sum, because we have reason to believe that customers and consumers are likely to suffer a substantial loss of competition as a result of the proposed transaction, and there are no demonstrated countervailing efficiencies, we believe the public interest is best served by accepting the proposed consent order to remedy our competitive concerns.

**Separate Statement of Commissioner Maureen K. Ohlhausen**

**ZF Friedrichshafen AG/TRW Automotive Holdings Corp.**

I voted in favor of issuing for public comment the proposed consent agreement in this matter. As discussed below, there is sufficient evidence to provide me with a reason to believe that, absent a remedy, the transaction is likely to violate Section 7 of the Clayton Act. I also find that the proposed consent, which is intended to remedy any such violation, is in the public interest.

Based on the evidence presented to me—including the evidence discussed in the Analysis to Aid Public Comment and the majority statement in this matter—I am satisfied that the ''reason to believe'' prong that the Commission must assess in issuing a complaint, including in the consent context, is met here. It is important to note that the Commission makes the reason to believe determination before a full evidentiary and legal record is developed during a trial on the merits, which suggests that the standard must necessarily be lower than what the Commission or a court should apply for finding ultimate liability. Individual Commissioners, of course, have different views on how much evidence is necessary to satisfy the reason to believe standard. Unfortunately, there does not appear to be a consensus view on what the standard requires. I respect Commissioner Wright's view that the standard was not met for him in this case. For the reasons identified in the majority statement in this matter, I determined that there is a credible basis on which to conclude that this merger may enhance the vulnerability to coordinated effects that already exists in the relevant market at issue.[1]

I further view this consent to be in the public interest. In my time as a Commissioner, I have advocated for transparency, predictability, and fairness across a variety of settings.[2] Those three critical goals apply equally to the merger context. A practical problem in our merger review process arises, however, where investigations are cut short by the merging parties, which, for business, strategic, or other reasons, offer staff and then ultimately the Commission a proposed remedy in lieu of responding to a Second Request or other compulsory process. In such cases, the available evidence may be sufficient to provide reason to believe the proposed transaction would violate Section 7, but a full investigation might (or might not) reveal additional evidence sufficient to counterbalance the available evidence and support closing the investigation altogether. In that situation, the goals of predictability and fairness counsel against forcing merging parties (and Commission staff) to incur the significant costs associated with a full-phase investigation. Merging parties also expend non-trivial amounts of time and money in developing and then proposing remedies to FTC staff; those good-faith efforts—particularly ones that involve coordination of remedies across antitrust jurisdictions—should not be discounted. The public interest analysis thus should take into account the need for predictability and fairness for merging parties in these circumstances.

**Dissenting Statement of Commissioner Joshua D. Wright**

**In the Matter of ZF Friedrichshafen AG and TRW Automotive Holdings Corp.**

The Commission has voted to issue a Complaint and Decision & Order against ZF Friedrichshafen AG (''ZF'') to remedy the allegedly anticompetitive effects of ZF's proposed acquisition of TRW Automotive Holdings Corp. (''TRW''). I respectfully dissent because the evidence is insufficient to provide reason to believe ZF's acquisition will substantially lessen competition for heavy vehicle tie rods sold in North America. In particular, I believe the Commission has not met its burden to show that the acquisition will result in an increased likelihood of harm from coordinated effects or from unilateral effects. As a consequence, the Commission should close the investigation and allow the parties to complete the proposed transaction without imposing a remedy.

I write separately today to explain my vote and to discuss the quality and quantity of evidence necessary to support a coordinated and unilateral effects challenge under the 2010 *Horizontal Merger Guidelines* (''*Merger Guidelines*'').

The Complaint alleges the proposed transaction increases the likelihood of coordinated effects and unilateral effects in the market for heavy vehicle tie rods sold in North America.[1] After the proposed transaction, ZF and TRW would have a combined 41% share. The remaining competitor, Urresko, has a 58% share. Fringe suppliers have a 1% share.

**I. Coordinated Effects Are Unlikely in the Relevant Market**

The Complaint implicates an important question with regard to coordinated effects: What evidence is necessary to establish reason to believe a proposed transaction may substantially lessen competition by ''enabling or encouraging post-merger coordinated interaction among firms in the relevant market that harms customers.''[2]

[15] *See* Press Release, European Commission, Mergers: Commission Clears Acquisition of Automotive Components Manufacturer TRW by Rival ZF, Subject to Conditions (Mar. 12, 2015), *available at http://europa.eu/rapid/press-release_IP-15-4600_en.htm.*

[1] *See 2010 Horizontal Merger Guidelines* § 7.1.

[2] Those settings have included the use of disgorgement in competition cases, the proper scope of our standalone Section 5 authority, the intersection of intellectual property and antitrust, and the treatment of U.S. businesses by foreign antitrust jurisdictions. *See, e.g.,* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *In re* Cardinal Health, Inc., FTC File No. 101–0006 (Apr. 17, 2015), *available at https://www.ftc.gov/public-statements/2015/04/dissenting-statement-commissioner-maureen-k-ohlhausen-cardinal-health-inc* (dissenting from consent involving disgorgement of profits for alleged Section 2 violation); Maureen K. Ohlhausen, *Section 5 of the FTC Act: Principles of Navigation,* 2 J. Antitrust Enforcement 1 (2014), *available at http://www.ftc.gov/public-statements/2013/10/section-5-ftc-act-principles-navigation-0* (advocating for additional guidance on the FTC's use of its standalone Section 5 authority); Dissenting Statement of Commissioner Maureen K. Ohlhausen, *In re* Motorola Mobility LLC & Google, Inc., FTC File No. 121–0120 (Jan. 3, 2013), *available at https://www.ftc.gov/public-statements/2013/01/statement-commissioner-maureen-ohlhausen-0* (dissenting from consent involving standalone Section 5 claim against holder of standard-essential patents); Testimony of Commissioner Maureen K. Ohlhausen, ''The Foreign Investment Climate in China: U.S. Administration Perspectives on the Foreign Investment Climate in China,'' before the U.S.-China Economic and Security Review Commission (Jan. 28, 2015), *available at https://www.ftc.gov/public-statements/2015/01/testimony-commissioner-maureen-k-ohlhausen-hearing-foreign-investment* (discussing importance of foreign antitrust jurisdictions pursuing the goals of predictability, transparency, and fairness).

[1] Compl. ¶ 12, ZF Friedrichshafen AG, FTC File No. 141–0235 (May 5, 2015).

[2] U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 7 (2010) [hereinafter Merger Guidelines].

The *Merger Guidelines* offer three conditions that, if satisfied, suggest the agency is likely to challenge a merger upon the basis that it will result in an increased likelihood of competitive harm from coordination. The *Merger Guidelines* specify that the agencies are likely to challenge a merger if: (1) ''the merger would significantly increase concentration and lead to a moderately or highly concentrated market;'' [3] (2) the ''market shows signs of vulnerability to coordinated conduct;'' [4] and (3) ''the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability.'' [5]

The second and third conditions are at issue here and worthy of further discussion.

The record evidence is mixed with respect to the second condition, whether the market shows signs of vulnerability to coordinated conduct. Evidence that the market is generally conducive to coordinated interaction includes the fact that heavy vehicle tie rods are fairly homogeneous goods and are purchased using relatively short-term contracts.

Also potentially germane to assessing the vulnerability of the relevant market to coordinated conduct are previous episodes of coordination by the same players in different markets. In 2012, a German subsidiary of TRW Automotive, TRW Deutschland Holding GmbH, pled guilty to a conspiracy to fix prices of seatbelts, airbags, and steering wheels sold to two German automobile customers for vehicles manufactured or sold in the United States.[6] While this prior episode does not involve the same relevant product or geographic markets as the current matter, it might suggest some vulnerability to coordination.[7]

There are other considerations, however, that indicate the market for heavy vehicle tie rods is not particularly vulnerable to coordination. First, while the product might be fairly homogeneous, there are significant switching costs including the time and cost involved with validation testing of the new supplier's tie rods. All else equal, significant switching costs make markets less vulnerable to coordination because they diminish firms' ability to punish effectively deviations from the coordinated price. Second, cost and demand fluctuations appear to be relatively frequent and large, which increase the information costs needed to detect accurately deviations.[8] Third, Urresko is a relatively recent entrant and has become the largest supplier in the market. These types of disruptive market events are generally not conducive to successful coordinated interactions. Finally, there are a number of large buyers, which can result in dramatic market share swings if a supplier loses the majority of a buyer's business. While the record evidence with respect to vulnerability of the relevant market is certainly mixed at best, it would not be unreasonable to find the second prong in the *Merger Guidelines* satisfied.

Ultimately, however, I do not have reason to believe the proposed transaction is likely to result in coordinated effects because the record evidence does not satisfy the third condition—that is, there is no ''credible basis on which to conclude that the merger may *enhance''* any pre-merger vulnerability to coordination.

The *Merger Guidelines* provide the acquisition of a maverick firm as one illustrative example of the type of evidence that would satisfy this third condition. There is no evidence that either ZF or TRW is a maverick firm as contemplated by the *Merger Guidelines.*

The sole evidence offered in favor of the proposition that the proposed transaction will *enhance* the market's vulnerability to coordination is that the merger will reduce the number of firms in the relevant market from three to two. I do not agree that a reduction of firms from three to two, without more, is enough to provide ''a credible basis to conclude that the merger may *enhance* that vulnerability.'' The observation that a market with N firms will, after the merger, have N–1 firms, is simply insufficient without more to establish the required credible basis under the *Merger Guidelines.* This is true even when a merger reduces the number of firms from three to two. The Commission offers no explanation as to why the *Merger Guidelines* would go through the trouble of requiring a credible basis to believe a merger will change the market's competitive dynamics that *enhances* the market's vulnerability to coordinated conduct, *in addition to* an increase in market concentration, in order to substantiate a coordinated effects merger challenge if the latter were considered sufficient to satisfy both elements.[9]

As I have stated previously, ''there is no basis in modern economics to conclude with any modicum of reliability that increased concentration—without more—will increase post-merger incentives to coordinate. Thus, the *Merger Guidelines* require the federal antitrust agencies to develop additional evidence that supports the theory of coordination and, in particular, an inference that the merger increases incentives to coordinate.'' [10] Janusz Ordover, in a leading treatment of the economics of coordinated effects, similarly explains that ''It is now well understood that it is not sufficient when gauging the likelihood of coordinated effects from a merger to simply observe that because the merger reduces the number of firms, it automatically lessens the coordination problem facing the firms and enhances

[3] *Id.* § 7.1.

[4] *Id.*

[5] *Id.*

[6] Plea Agreement ¶ 4(e)–(f), United States v. TRW Deutschland Holding GmbH, No. 2:12–cr–20491–GCS–PJK (E.D. Mich. Sept. 25, 2012).

[7] The *Merger Guidelines* state that ''The Agencies presume that market conditions are conducive to coordinated interaction if firms representing a substantial share in the relevant market appear to have previously engaged in express collusion affecting the relevant market,'' but that prior ''express collusion in another geographic market will have the same weight if the salient characteristics of that other market at the time of the collusion are comparable to those in the relevant market,'' and that prior collusion ''in another product market may also be given substantial weight if the salient characteristics of that other market at the time of the collusion are closely comparable to those in the relevant market.'' Merger Guidelines, supra note 2, § 7.2. Thus, I am comfortable with concluding the prior TRW Deutschland price-fixing case is material to our investigation, and that this evidence increases the likelihood of coordination, all things equal. However, without a more detailed assessment of any logical connection between the markets where collusion actually took place and the relevant market here, I am hesitant to give this factor alone substantial weight given observable differences between the markets. For instance, in the markets at issue in that case, the bidding process appeared to be more formal with longer commitments. *See* Information ¶ 8, United States v. TRW Deutschland Holding GmbH, No. 2:12–cr–20491–GCS–PJK (E.D. Mich. July 30, 2012).

[8] For instance, the primary input to produce heavy vehicle tie rods is steel. Looking at the producer price index for steel mill products, the average annual price change over the past ten years is 1.6% with a standard deviation of 6.6%. Some of the specific yearly changes are substantial, *e.g.,* −8.6%, 7.5%, 9.1%, 12.8%. *Producer Price Index—Metals and Metal Products,* U.S. Bureau of Labor Statistics, *http://www.bls.gov/regions/mid-atlantic/data/ProducerPriceIndexMetals_US_Table.htm* (last visited May 8, 2015).

[9] The Commission cites Carl Shapiro to support the proposition that market concentration is relevant to coordinated effects analysis. *See* Statement of the Federal Trade Commission 2 n.4, ZF Friedrichshafen AG, FTC File No. 141–0235 (May 8, 2015) (quoting Carl Shapiro, *The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years,* 77 Antitrust L.J. 701, 708 (2010) (''In particular, as the revised Guidelines explain, the Agencies place considerable weight on HHI measures in cases involving coordinated effects.'')). I agree. The 2010 *Merger Guidelines* establish market concentration as one of three conditions that must be satisfied to find coordinated effects. What Shapiro does not state, and the proposition the Commission does not otherwise substantiate, is that evidence of changes in market concentration is sufficient to satisfy the third condition along with the first.

[10] Dissenting Statement of Commissioner Joshua D. Wright 3, Fidelity National Financial, Inc., FTC File No. 131–0159 (Dec. 23, 2013).

their incentives to engage in tacit collusion; far from it.'' [11] The required additional evidence needed to satisfy the third condition is absent in this case.

## II. Unilateral Effects Are Unlikely in the Relevant Market

The sole evidence offered in favor of the Commission's allegation that the merger will render unilateral price effects likely is that some customers have used the competition between ZF and TRW to obtain better pricing and some customers have switched between the two suppliers.[12] While this is certainly material to our inquiry, this is a thin reed, without more, upon which to base a unilateral price effects case. There is no information on price effects. Moreover, there is no substantial evidence on the record with respect to the role the market leader, Urresko, plays in disciplining prices. The fact that Urresko is a recent entrant and has become the market leader in a relatively short period of time also renders dubious the proposition that barriers to entry in the relevant market are adequate to sustain a post-merger price increase. Additionally, even with sufficient barriers, Urresko's rapid growth undermines significantly any unilateral effects argument and suggests a post-merger price increase from a merged ZF–TRW would be fragile and potentially unsuccessful. The *Merger Guidelines* contemplate the possibility of intense competition in markets with small numbers of firms, observing that ''Even a highly concentrated market can be very competitive if market shares fluctuate substantially over short periods of time in response to changes in competitive offerings.'' [13]

Moreover, unilateral effects in a homogeneous goods market principally involve reductions in output.[14] In order to be profitable, the reduction in output must not be met by a sufficient supply response by rivals. Thus, absent meaningful capacity constraints, unilateral effects are less likely in homogeneous goods markets. I have seen no evidence that Urresko is capacity constrained.

## III. Conclusion

The Commission insists that a different ''lens'' should be used to evaluate evidence in markets where the number of firms is reduced by merger to three or two.[15] The Commission cites in support of its structural theory and presumption three academic articles written by economists.[16] Only two offer economic evidence and the proffered substantiation fails to support the claim. The first is an important early entrant into the static entry literature examining the relationship between market size and the number of entrants in a market, focusing upon isolated rural markets.[17] It strains credulity to argue that Bresnahan and Reiss's important analysis of the impact of entry in markets involving doctors, dentists, druggists, plumbers, and tire dealers in local and isolated areas, where they find the competitive benefits of a second competitor are especially important, apply with generality sufficient to support a widely applicable presumption of harm based upon the number of firms. Indeed, the authors warn against precisely this interpretation of their work.[18]

The second is a laboratory experiment and does not involve the behavior of actual firms and certainly cannot provide sufficient economic evidence to support a presumption that four-to-three and three-to-two mergers in real-world markets will result in anticompetitive coordination.[19] Once again, the authors warn against such an interpretation.[20]

Finally, the Commission cites a draft article, authored by Steve Salop, in support of its view that economic evidence supports a presumption that four-to-three and three-to-two mergers are competitively suspect.[21] The article does not purport to study or provide new economic evidence on the relationship between market structure and competition. Thus, it cannot support the Commission's proposition.[22] In sum, there is simply no empirical economic evidence sufficient to warrant a *presumption* that anticompetitive coordination is likely to result from four-to-three or three-to-two mergers.

It is important to note that the Commission and I have no disagreement over the proposition that the number of competitors within a market is a relevant fact to assess the likely competitive effects of a transaction. The relevant question is not whether the number of firms matters but how much it matters—and in particular, whether a movement to three or two firms warrants a generally applicable presumption that a transaction is more likely than not to harm competition. I do not believe it does. The Commission disagrees.

The *Merger Guidelines* make clear that the purpose of market concentration and market shares associated thresholds ''is not to provide a rigid screen to separate competitive benign mergers from anticompetitive ones, although high levels of concentration do raise concerns.'' [23]

[11] Janusz A. Ordover, *Coordinated Effects, in* 2 Issues in Competition Law and Policy 1359, 1367 (ABA Section of Antitrust Law 2008) (''It is quite clear . . . that a reduction in the number of firms and concomitant increases in concentration do not necessarily make collusion inevitable or even more likely, stable, or complete.'').

[12] *See* Analysis of Agreement Containing Consent Order to Aid Public Comment 2, ZF Friedrichshafen AG, FTC File No. 141–0235 (May 5, 2015).

[13] Merger Guidelines § 5.3, *supra* note 2.

[14] *See id.* § 6.3.

[15] *See* Statement of the Federal Trade Commission, *supra* note 9, at 2.

[16] *Id.* at 2 n.5.

[17] Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets,* 99 J. Pol. Econ. 977 (1991). While Bresnahan and Reiss is an important early contribution to the static entry literature, it cannot possibly bear the burden the Commission wishes to place upon it. Abstracting from the complexities of market definition was necessary for the researchers to isolate entry decisions. This is possible when studying the effects of entry by a second dentist in a town with a population of less than 1,000, but not in most real-world antitrust applications. The authors of the study make this point themselves, noting that ''whether this pattern appears in other industries remains an open question.'' *Id.* at 1007.

[18] In earlier research using similar empirical techniques and data—namely, small rural markets—Bresnahan and Reiss plainly reject the notion that the findings should inform views of market structure and competition generally: ''We do not believe that these markets 'stand in' for highly concentrated industries in the sectors of the economy where competition is national or global.'' Timothy F. Bresnahan & Peter C. Reiss, *Do Entry Conditions Vary Across Markets,* 3 Brookings Papers Econ. Activity 833, 868 (1987).

[19] Steffen Huck et al., *Two Are Few and Four Are Many: Number Effects from Experimental Oligopolies,* 53 J. Econ. Behavior & Org. 435 (2004).

[20] *Id.* at 436 (''The number of firms is not the only factor affecting competition in experimental markets. This implies that there exists no unique number of firms that determines a definite borderline between non-cooperative and collusive markets irrespective of all institutional and structural details of the experimental markets.'').

[21] Steven C. Salop, *The Evolution and Vitality of Merger Presumptions: A Decision-Theoretic Approach* (Georgetown Law Faculty Publications and Other Works, Working Paper No. 1304, 2014), *available at http://scholarship.law.georgetown.edu/facpub/1304/.*

[22] Nevertheless, to the extent Salop argues in favor of legal presumptions in merger analysis, he clarifies that they ''obviously should be based on valid economic analysis, that is, proper economic presumptions,'' which should be updated ''based on new or additional economic factors besides market shares and concentration.'' *Id.* at 37, 48. I agree. Additionally, Salop explains that ''[c]ontemporary economic learning suggests that concentration be considered when undertaking competitive effects analysis—in conjunction with other factors suggested by the competitive effects theory—but not treated as the sole determinant of post-merger pricing.'' *Id.* at 13–14. Notably, Salop does not endorse a distinction between four-to-three mergers or three-to-two mergers and mergers in less concentrated markets that justifies a presumption that the former are anticompetitive; rather, he merely observes that empirical evidence and economic theory do not warrant ''*ignoring* market shares and concentration in merger analysis.'' *Id.* at 12 (emphasis in original).

[23] Merger Guidelines, *supra* note 2, § 5.3.

Rather concentration is but one aspect of the inquiry aimed at better understanding post-merger incentives to compete. The predictive power of market share and market concentration data is informed by economic theory and available empirical evidence. There is no empirical evidence sufficient to establish a generally applicable presumption that mergers that reduce the number of firms to three or two are likely to harm competition.[24] Further, the Commission's reliance upon such shorthand structural presumptions untethered from empirical evidence subsidize a shift away from the more rigorous and reliable economic tools embraced by the *Merger Guidelines* in favor of convenient but obsolete and less reliable economic analysis.

This is not to say that evidence of changes in market structure cannot ever warrant such a presumption. It does when the evidence warrants as much. The Commission has in certain contexts found reason to believe competition would be substantially lessened based simply upon a reduction of firms in the relevant market. See *Actavis plc-Forest Laboratories* [25] and also *Akorn-Hi-Tech Pharmacal,*[26] which both involve generic pharmaceutical markets. The Commission was able to draw conclusions about the relationship between price and the number of firms in generic pharmaceutical markets because substantial research has been done to establish that such a relationship exists.[27] Indeed, the cases in the pharmaceutical industry are the exceptions that prove the rule that the Commission needs to do more than count the number of firms in a market to have reason to believe a substantial lessening of competition is likely. No such research has been done in this market. Accordingly, unlike in generic pharmaceutical markets, we have no evidence to conclude that a simple reduction in the number of firms in this market is likely to lead to higher prices and lower output. Simply assuming such a relationship exists in this market without any evidence to suggest that it does harkens back to the bad old days of the first half of the 20th century, when the structure-conduct-performance paradigm was in vogue.

To summarize, there are three-to-two mergers that give rise to unilateral effects, and three-to-two mergers that give rise to coordinated effects. It is our burden to show that *this* three-to-two merger is likely anticompetitive. The Commission must find sufficient evidence to support an inference of likely economic harm to consumers. The heavy degree of reliance upon a structural presumption in this case is not sufficient to do so.

Finally, the Commission and Commissioner Ohlhausen each claim that the quantity, and presumably the quality, of the evidence is not the same for investigations truncated by remedy proposals compared to cases where a full phase investigation is completed or compared to a completed trial, respectively.[28] While this observation is an accurate description of the pragmatic reality of conducting law enforcement investigations, I do not agree with the implication that the quantum and quality of evidence needed to satisfy the ''reason to believe'' standard should turn on whether and when a remedy proposal is offered during an investigation. The idea is that we should ''take into account the need for predictability and fairness for merging parties in these circumstances'' [29] and considerations whether it is ''appropriate to subject the parties to the added expense and delay of a full phase investigation.'' [30] I fully support the agency identifying opportunities to lower the administrative costs of antitrust investigations and believe there to be ample opportunity to do so. But attempts to operate a more efficient law enforcement system must satisfy the constraint, required by law, that there is reason to believe a transaction violates Section 7 of the Clayton Act. That standard sets a relatively low bar for the minimum level of evidence required to substantiate a merger challenge. I reject the view that it should be a standard that should be relaxed because the merging parties offer a remedy.[31] The Commission is primarily a law enforcement agency, albeit one that largely conducts it business by entering into consents with merging parties. Making the consent process more efficient and predictable is a laudable goal; but we must not allow pursuit of a more efficient consent process to distort our evaluation of the substantive merits. To do so, as in my view we have here, risks in the long run reducing the institutional capital of the agency in magnitudes far greater than any potential cost savings from truncating an investigation.

For these reasons, I cannot join my colleagues in supporting the consent order because I do not have reason to believe the transaction violates Section 7 of the Clayton Act nor that a consent ordering divestiture is in the public interest.

[FR Doc. 2015–11721 Filed 5–14–15; 8:45 am]

BILLING CODE 6750–01–P

[24] *See* Statement of Commissioner Joshua D. Wright 3–5, Holcim Ltd., FTC File No. 141–0129 (May 8, 2015).

[25] Analysis of Agreement Containing Consent Orders to Aid Public Comment 2, Actavis plc, FTC File No. 141–0098 (June 30, 2014) (''In generic pharmaceutical product markets, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market would likely have a direct and substantial anticompetitive effect on pricing.'').

[26] Analysis of Agreement Containing Consent Orders to Aid Public Comment 3, Akorn Enterprises, Inc., FTC File No. 131–0221 (Apr. 14, 2014) (''In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply.'').

[27] *See* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics,* 87 Rev. Econ. & Stat. 37 (2005). As an aside, given that we are now ten years removed from the publication of this important study and over twenty years removed from the sample period, it might be worth revisiting this question with fresher data if the Commission intends to continue relying upon inferences of competitive harm from market structure in the generic pharmaceutical market.

[28] *See* Statement of the Federal Trade Commission, *supra* note 9, at 3 n.7; *see also* Separate Statement of Commissioner Maureen K. Ohlhausen 1, ZF Friedrichshafen AG, FTC File No. 141–0235 (May 8, 2015).

[29] Separate Statement of Commissioner Maureen K. Ohlhausen, *supra* note 28, at 2.

[30] Statement of the Federal Trade Commission, *supra* note 9, at 3 n.7.

[31] That said, as I stated in *Holcim Ltd.,* I am not suggesting the ''reason to believe'' standard ''requires access to every piece of relevant information and a full and complete economic analysis of a proposed transaction, regardless of whether the parties wish to propose divestitures before complying with a Second Request.'' *See* Statement of Commissioner Joshua D. Wright, *supra* note 24, at 11.

## FEDERAL TRADE COMMISSION

**[File No. 141 0129 ]**

## Holcim Ltd. and Lafarge S.A.; Analysis of Proposed Consent Orders To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before June 4, 2015.

**ADDRESSES:** Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/holcimlafargeconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Holcim Ltd. and Lafarge

SA—Consent Agreement; File No. 141–0129'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/holcimlafargeconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Holcim Ltd. and Lafarge SA—Consent Agreement; File No. 141–0129'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** James Southworth, Bureau of Competition, (202–326–2822), 600 Pennsylvania Avenue NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 4, 2015), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 4, 2015. Write ''Holcim Ltd. and Lafarge SA—Consent Agreement; File No. 141–0129'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/holcimlafargeconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Holcim Ltd. and Lafarge SA—Consent Agreement; File No. 141–0129'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 4, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

**Analysis of Agreement Containing Consent Orders To Aid Public Comment**

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') designed to remedy the anticompetitive effects resulting from the proposed acquisition of Lafarge S.A (''Lafarge'') by Holcim Ltd. (''Holcim''). Under the terms of the proposed Consent Agreement, Lafarge is required to divest to Continental Cement Company (''Continental'') its Davenport cement plant and quarry located in Buffalo, Iowa along with cement terminals and associated distribution assets in Minneapolis and St. Paul, Minnesota; La Crosse, Wisconsin; Memphis, Tennessee; and Convent and New Orleans, Louisiana. The Consent Agreement also requires Holcim to divest its Skyway slag cement plant located in Chicago, Illinois to Eagle Materials Inc. (''Eagle''), its slag cement plant located in Camden, New Jersey and its terminal near Boston, Massachusetts to Essroc Cement Corporation (''Essroc''), and its cement terminals in Grandville and Elmira, Michigan and Rock Island, Illinois to Buzzi Unicem USA (''Buzzi''). Finally, the Consent Agreement requires Holcim to divest to a buyer or buyers approved by the Commission (1) Holcim's Trident, Montana cement plant and two related terminals in Alberta, Canada, and (2) Holcim's Mississauga cement plant located in Ontario, Canada and related cement terminals in Duluth, Minnesota; Detroit and Dundee, Michigan; Cleveland, Ohio; and Buffalo, New York.

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make final the Decision and Order (''Order'').

**The Transaction**

Pursuant to a Combination Agreement dated July 7, 2014, Holcim proposes to acquire 100 percent of the existing shares of Lafarge in a transaction valued at $24.95 billion at that time. The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in certain regional markets in the United States for the manufacture and sale of portland cement and slag cement. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the proposed acquisition.

**The Parties**

Holcim is a Swiss-based, vertically integrated global building materials company. The company's products include cement, clinker, concrete, lime, and aggregates. In the United States, Holcim currently operates nine portland cement and three slag grinding plants, as well as a large network of distribution assets.

Lafarge is a vertically-integrated global building materials company incorporated in France and headquartered in Paris. Lafarge primarily produces and sells cement, aggregates, and ready-mix concrete. In the United States, Lafarge currently operates six portland cement and three slag cement grinding plants as well as numerous distribution terminals.

**The Relevant Products and Structure of the Markets**

In the United States, both parties manufacture and sell portland cement. Portland cement is an essential ingredient in making concrete, a cheap and versatile building material. Because portland cement has no close substitute and the cost of cement usually represents a relatively small percentage of a project's overall construction costs, few customers are likely to switch to other products in response to a small but significant increase in the price of portland cement.

Both parties also manufacture and sell ground, granulated blast furnace slag (''slag cement''), a specialty cement product with unique characteristics that can serve as a partial substitute for portland cement. Customers add slag cement to portland cement to enhance the physical properties of a concrete mixture. It is appropriate to treat slag cement as a separate relevant product because an insufficient number of purchasers would switch to other products in response to a small but significant increase in the price of slag cement to render such a price increase unprofitable.

The primary purchasers of portland and slag cement are ready-mix concrete firms and producers of concrete products. These customers usually pick up portland and slag cement from a cement company's plant or terminal in trucks. Because portland and slag cement are heavy and relatively cheap commodities, transportation costs limit the distance customers can economically travel to pick up the products. The precise scope of the area that can be served by a particular plant or terminal depends on a number of factors, including the density of the specific region and local transportation costs.

Due to transportation costs, cement markets are local or regional in nature. The relevant geographic markets in which to analyze the effects of the proposed acquisition on portland cement competition are (1) the Minneapolis-St. Paul, Minnesota area; (2) the Duluth, Minnesota area; (3) western Wisconsin; (4) eastern Iowa; (5) the Memphis, Tennessee area; (6) the Baton Rouge, Louisiana area; (7) the New Orleans, Louisiana area; (8) the Detroit, Michigan area; (9) northern Michigan; (10) the Grand Rapids, Michigan area; (11) western Montana; and (12) the Boston, Massachusetts/Providence, Rhode Island area. The proper geographic markets in which to analyze the effects of the proposed transaction on slag cement are (1) the Mid-Atlantic region and (2) the western Great Lakes region.

The relevant markets for portland cement and slag cement are already highly concentrated. For each of the relevant markets, the parties are either the only suppliers in the market, two of only three suppliers, or two of only four suppliers.

**Entry**

Entry into the relevant portland cement and slag cement markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed transaction. The cost to construct a new portland cement plant of sufficient size to be competitive would likely cost over $300 million and take more than five years to permit, design, and construct while the expansion of an existing facility would likely cost hundreds of millions of dollars and take four or more years to complete. Building competitive cement distribution terminals is also difficult and time consuming. It can take more than two years to obtain the necessary permits and complete construction of a competitive terminal in the relevant markets. New entrants into slag cement markets face the additional hurdle of having to obtain a cost-effective source for the raw material. There are few domestic sources for granulated blast furnace slag because there are a limited number of active blast furnaces in the United States. Given the difficulties of entry, it is unlikely that any new entry could be accomplished in a timely manner in the relevant markets to defeat a likely price increase caused by the proposed acquisition.

**Effects of the Acquisition**

Unless remedied, the proposed merger would likely result in competitive harm in each of the relevant portland and slag cement markets. The merger would eliminate substantial head-to-head competition between the parties in each of these markets and significantly increase market concentration. For many customers in these markets, the merger would combine the two closest competitors for their business, leaving the merged entity with the power to increase prices to these customers unilaterally. Further, because the merger would reduce the number of significant competitors to, at most, two or three in the relevant markets, it would enhance the likelihood of collusion or coordinated action between the remaining competitors by reducing impediments to reaching common terms of coordination and making it easier to monitor and retaliate against potential deviation from a coordinated scheme.

**The Consent Agreement**

The proposed Consent Agreement eliminates the competitive concerns raised by Holcim's proposed acquisition of Lafarge by requiring the parties to divest assets in each relevant market. Lafarge is required to divest a cement plant in Buffalo, Iowa and a network of distribution terminals along the Mississippi River in Louisiana, Tennessee, Wisconsin, and Minnesota to Continental. Continental, in turn, will sell its cement terminal located in Bettendorf, Iowa to Lafarge in order to eliminate the competitive overlap that would otherwise be created by its acquisition of Lafarge's Davenport cement plant. Because Lafarge will be

able to supply the Bettendorf terminal at a comparable or lower cost than Continental, the transactions contemplated in the Consent Agreement will maintain the competitive status quo in the eastern Iowa market. Holcim is required to divest distribution terminals in Illinois and Michigan to Buzzi. Holcim is further required to divest a terminal in Massachusetts and a slag plant in New Jersey to Essroc and a slag plant in Illinois to Eagle. Each of the identified buyers possesses the experience and capability to become significant competitors in the relevant markets. The parties must accomplish the divestitures to these buyers within ten days after the proposed acquisition is accomplished.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that any of the identified buyers is not an acceptable acquirer, the proposed Order requires the parties to divest the assets to a Commission-approved acquirer within 90 days of the Commission notifying the parties that the proposed acquirer is not acceptable. If the Commission determines that the manner in which any divestiture was accomplished is not acceptable, the Commission may direct the parties, or appoint a divestiture trustee, to effect such modifications as may be necessary to satisfy the requirements of the Order.

Finally, the proposed Consent Agreement requires Holcim to divest to a buyer or buyers approved by the Commission (1) a cement plant in Trident, Montana and two distribution terminals in Alberta, Canada (the ''Trident Assets''), and (2) a cement plant in Mississauga, Ontario and cement terminals in Minnesota, Michigan, Ohio, and New York (the ''Great Lakes Assets''). The divestiture of the Trident plant would eliminate the proposed merger's potential anticompetitive impact on purchasers of portland cement located in western Montana. The two Alberta terminals distribute cement produced at the Trident plant and are included in the Consent Agreement in order to preserve the viability and marketability of the Trident Assets. Holcim's Mississauga plant supplies portland cement into the United States both directly and via terminals located in Duluth; Detroit; Dundee, Michigan; Cleveland, Ohio; and Buffalo, New York. The divestiture of the Great Lakes Assets would remedy the proposed merger's anticompetitive effects in the Duluth and Detroit areas. The Cleveland and Buffalo terminals are included in the Consent Agreement in order to preserve the viability and marketability of the Great Lakes Assets. The Trident Assets and Great Lakes Assets are also part of a larger group of Holcim assets located in Canada that the Respondents have agreed to divest in order to resolve competitive concerns raised by the Canadian Competition Bureau (''CCB''). Commission staff worked cooperatively with staff from the CCB to ensure that our respective proposed remedies would be consistent and effective.

The proposed Order provides that Holcim must find a buyer (or buyers) for the Trident Assets and the Great Lakes Assets, at no minimum price, that is acceptable to the Commission, no later than 120 days from the date on which the parties consummate the proposed acquisition. The Consent Agreement also contains an Order to Hold Separate and Maintain Assets, which will serve to ensure that these assets are held separate and operated independently from the merged company and protect the viability, marketability, and competitiveness of the divestiture asset packages until the assets are divested to a buyer or buyers approved by the Commission.

To ensure compliance with the proposed Order, the Commission has agreed to appoint an Interim Monitor to ensure that Holcim and Lafarge comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to appropriate purchasers.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission, Commissioner Wright dissenting.

**Donald S. Clark,**

*Secretary.*

## Statement of the Federal Trade Commission in the Matter of Holcim Ltd. and Lafarge S.A.

The Federal Trade Commission has voted to accept a settlement to resolve the likely anticompetitive effects of Holcim Ltd.'s (''Holcim'') proposed $25 billion acquisition of Lafarge S.A. (''Lafarge''). We have reason to believe that, absent a remedy, the proposed acquisition is likely to substantially reduce competition in the manufacture and sale of portland cement and slag cement. As we explain below, we believe the proposed remedy, tailored to counteract the likely anticompetitive effects of the proposed acquisition without eliminating any efficiencies that might arise from the combination of the two companies, is in the public interest.[1]

Holcim is a Switzerland-based, vertically integrated global building materials company, with products that include cement, clinker, concrete, lime, and aggregates. Lafarge is a France-based, vertically integrated global building materials company that primarily produces and sells cement, aggregates, and ready-mix concrete.

The merged company will be the world's largest cement manufacturer, with combined 2014 revenues of approximately $35 billion and operations in more than 90 countries. Our competitive concerns pertain to specific geographic markets in the United States where Holcim and Lafarge each make significant cement sales. The proposed merger would likely harm competition for the distribution and sale of portland cement, an essential ingredient in making concrete, in 12 local or regional markets. It would also threaten to lessen competition for the distribution and sale of slag cement, a specialty cement product used in certain applications, in two other regional markets.

The merger would create a merger to monopoly in some of the challenged relevant markets, while in others at most three competitors would remain post-merger. Absent a remedy, the Herfindahl-Hirschman Index (''HHI'') in each of these markets would exceed 3,400, making every market highly concentrated according to the 2010 Horizontal Merger Guidelines.[2] The increase in HHI in each market would exceed 900, well above the 200-point change necessary to trigger the Guidelines' presumption that the merger is ''likely to enhance market power.''[3] There is no evidence rebutting this presumption. If anything, the evidence suggests that the estimates of market concentration understate our concerns.

In each of the relevant markets at issue, there is evidence that unilateral anticompetitive effects are likely. Substantial evidence demonstrates that, for many customers in the relevant areas, the merging firms are their preferred suppliers and that customers have benefitted from substantial head-to-head competition between the parties

[1] Chairwoman Ramirez, Commissioner Brill, Commissioner Ohlhausen, and Commissioner McSweeny join in this statement.

[2] *See* 2010 Horizontal Merger Guidelines § 5.3. The threshold at which a market is considered ''highly concentrated'' under the Guidelines is 2,500.

[3] *Id.*

in negotiating prices for portland and slag cement. Customers in every single one of the affected markets expressed concern that their inability to play the merging parties off each other would diminish their ability to obtain better prices or other favorable terms. As the Guidelines note, a combination of two competing sellers ''can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it, and less favorable to the buyer, than the merging firms would have offered separately absent the merger.''[4] In addition, the evidence demonstrates that not all of the remaining suppliers in the relevant markets provide customers with practical alternatives to the merging parties for a variety of reasons, including capacity constraints, lack of distribution assets to supply new customers, and downstream vertical integration.[5]

The evidence also suggests that the proposed acquisition would increase the ability and incentives of the combined firm and other market participants to engage in coordinated behavior that would result in harm to consumers. The relevant markets have characteristics that make them susceptible to coordination. They are highly concentrated; the products are homogeneous; overall market elasticity is low; customer switching costs are low; and sales are relatively small, frequent, and usually not made pursuant to long-term contracts. There is also a high degree of transparency in these markets. Competitors are aware of each other's production capacities, costs, sales volumes, prices, and customers. Our concern about the potential for coordinated effects in these markets is heightened by evidence that cement suppliers, including the same global firms that compete in these markets, have expressly colluded in other geographic markets with similar characteristics.[6] By reducing the number of significant competitors to only two or three, the proposed merger would make it easier for the remaining firms to coordinate, monitor compliance with, and retaliate against potential deviation from, a coordinated scheme. We therefore have reason to believe that the merger may enhance the vulnerability to coordinated effects that already exists in the relevant markets.[7]

In his dissent, Commissioner Wright takes issue with our decision to seek a remedy in six markets, going to great lengths to argue that we are improperly relying solely on the increase in market concentration to justify our action, that we are creating new presumptions of harm, that we lack a ''credible basis'' on which to conclude that the merger may enhance the vulnerability of the relevant markets to coordination, and that our action is otherwise inconsistent with the Guidelines. We respectfully disagree with Commissioner Wright's various characterizations of the Commission's statement in this matter. The Guidelines make clear that a substantial increase in concentration caused by a merger continues to be a significant factor in merger analysis because highly concentrated markets with only two or three large firms are more likely to lead to anticompetitive outcomes.[8] Economic theory and empirical research bear this out.[9] As a result, we view the evidence in a merger that reduces the number of firms in a relevant market to two or three differently from a merger that only reduces the number of firms to six or seven. Where, as here, a proposed merger significantly increases concentration in an already highly concentrated market, a presumption of competitive harm is justified under both the Guidelines and well-established case law.[10]

Moreover, despite Commissioner Wright's assertion to the contrary, our investigation went beyond consideration of market concentration and application of the Guidelines presumption of competitive harm and, as noted above, produced additional evidence supporting our belief that the effect of the proposed acquisition would be to substantially lessen competition and harm cement customers in the relevant markets. On coordinated effects, we found numerous characteristics of the market making it vulnerable to collusion. It is particularly troubling that existing cement suppliers have expressly colluded in other geographic markets with similar characteristics. We also examined whether other market factors, such as the possibility of entry or expansion, might alleviate our competitive concerns. The evidence demonstrates the presence of high barriers to entry for both portland cement and slag cement, including significant capital costs and regulatory requirements. Entry sufficient to deter or counteract the likely harm from the proposed transaction would thus be neither timely nor likely.

[4] *Id.* § 6.2.

[5] For instance, ready-mix concrete producers are often unwilling to purchase cement from their rivals.

[6] *See, e.g.,* Press Release, European Commission, The Court of Justice Upholds in Substance the Judgment Delivered by the Court of First Instance in 2000 Concerning the Cement Cartel, Jan. 7, 2004, *available at http://europa.eu/rapid/press-release_CJE–04–2_en.htm* (announcing fines of EUR 100 million on cement suppliers for collusion); Press Release, German Federal Cartel Office, Highest fine in Bundeskartellamt History is Final, April 10, 2013, *available at http://www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2013/10_04_2013_BGH-Zement.html* (announcing fines of EUR 380 million on Lafarge, Holcim, and others for collusion); Philip Blenkinsop, *Belgian Competition Regulator Fines Cement Groups,* Aug. 31, 2013, *available at http://www.reuters.com/article/2013/08/31/belgium-cement-idUSL6N0GW05U20130831* (reporting EUR 14.7 million in fines levied by the Belgian Competition Council on Holcim and others for collusion); Press Release, Polish Office of Competition and Consumer Protection, UOKiK Breaks Cement Cartel, Dec. 12, 2013, *available at https://uokik.gov.pl/news.php?news_id=10754&news_page=1* (announcing decision of Poland's Court of Competition and Consumer Protection to impose fines of PLN 339 million (~$93 million) on cement suppliers for collusion involving Lafarge and others); *see generally* Merger Guidelines § 7.2.

[7] *See* Merger Guidelines § 7.1.

[8] *Id.* § 2.1.3 (''Mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power, but this presumption can be rebutted by persuasive evidence showing that the merger is unlikely to enhance market power.''). *See also* Carl Shapiro, *The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years,* 77 Antitrust L.J. 701, 708 (2010) (explaining that the Guidelines' flexible approach ''certainly does *not* mean that they reject the use of market concentration to predict competitive effects, as can be seen in Sections 2.1.3 and 5,'' that the Guidelines ''recognize that levels and changes in market concentration are more probative in some cases than others,'' and that ''the Agencies place considerable weight on HHI measures in cases involving coordinated effects'') (emphasis in original).

[9] *See, e.g.,* Steven C. Salop, *The Evolution and Vitality of Merger Presumptions: A Decision-Theoretic Approach* 11 (Georgetown Law Faculty Publications and Other Works, Working Paper No. 1304, 2014), *available at http://scholarship.law.georgetown.edu/facpub/1304* (''[V]arious theories of oligopoly conduct—both static and dynamic models of firm interaction—are consistent with the view that competition with fewer significant firms on average is associated with higher prices. . . . Accordingly, a horizontal merger reducing the number of rivals from four to three, or three to two, would be more likely to raise competitive concerns than one reducing the number from ten to nine, *ceteris paribus.*''); Steffen Huck, et al., *Two Are Few and Four Are Many: Number Effects from Experimental Oligopolies,* 53 J. Econ. Behavior & Org. 435, 443 (2004) (testing the frequency of collusive outcomes in Cournot oligopolies and finding ''clear evidence that there is a qualitative difference between two and four or more firms''); Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets,* 99 J. Pol. Econ. 977, 1006 (1991) (finding, in a study of tire prices, that ''[m]arkets with three or more dealers have lower prices than monopolists or duopolists,'' and noting that, ''while prices level off between three and five dealers, they are higher than unconcentrated market prices'').

[10] *See* Merger Guidelines § 2.1.3; *Chicago Bridge & Iron Co.* v. *FTC,* 534 F.3d 410, 423 (5th Cir. 2008) (''Typically, the Government establishes a *prima facie* case by showing that the transaction in question will significantly increase market concentration, thereby creating a presumption that the transaction is likely to substantially lessen competition.''); *FTC* v. *H.J. Heinz Co.,* 246 F.3d 708, 716 (D.C. Cir. 2001) (merger to duopoly creates a rebuttable presumption of anticompetitive harm through direct or tacit coordination).

In the face of our competitive concerns, based on what we had learned about the nature and conditions of the relevant markets, the parties proposed divestitures to remedy our concerns in each of those markets. The parties did not comply with our Second Requests. While continued investigation may have produced more evidentiary support for our complaint, including those markets for which Commissioner Wright dissents, we do not think such a course would have been justified. We have ample evidence to support our allegations of anticompetitive harm and had no reason to burden the parties with the expense and delay of further inquiry for the sole purpose of obtaining additional, cumulative evidence. Nor would further inquiry have been a good use of Commission resources.

Merger analysis is necessarily predictive. The evidence in this case provides us with sufficient reason to believe that the proposed acquisition is likely to substantially reduce competition, and there is no evidence of countervailing efficiencies that weigh against the remedy. We believe that the public interest is best served by remedying the competitive concerns as set forth in our proposed consent order.

**Statement of Commissioner Joshua D. Wright, Dissenting in Part and Concurring in Part In the Matter of Holcim Ltd. and Lafarge S.A.**

The Commission has voted to issue a Complaint and a Decision & Order against Holcim Ltd. (''Holcim'') and Lafarge S.A. (''Lafarge'') to remedy the allegedly anticompetitive effects of the proposed merger of the two companies. I dissent in part from and concur in part with the Commission's decision because the evidence is insufficient to provide a reason to believe the proposed transaction is likely to substantially lessen competition, in violation of Section 7 of the Clayton Act, in several of the portland cement markets identified in the Complaint.[1]

The Commission articulates coordinated effects and unilateral effects theories of harm arising from the proposed transaction in all of the fourteen relevant geographic markets defined in the Complaint (the ''Relevant Markets'').[2] Additionally, and untethered to these two theories of harm articulated in the 2010 *Horizontal Merger Guidelines* (''*Merger Guidelines*''), the Commission asserts that mergers, such as the proposed transaction, that reduce the number of competitors to three or fewer are likely to harm competition. The Commission's structural presumption is economically unfounded and inappropriate in the vast majority of Relevant Markets. Furthermore, there is insufficient evidence to support a coordinated effects theory in any Relevant Market and insufficient evidence to support a unilateral effects theory in several of the Relevant Markets.

In those markets in which I conclude the record evidence supports neither a coordinated nor a unilateral effects theory, the Commission relies upon little more than the change in market structure to support each of its allegations. Without particularized evidence substantiating a unilateral effects or coordinated effects theory of harm arising from the proposed transaction, a structural theory alone cannot provide a sufficient basis to establish reason to believe a transaction violates the Clayton Act. It follows, in my view, that the Commission should refrain from imposing a remedy in the markets for which the evidence is insufficient to support either a coordinated effects theory or a unilateral effects theory.

**I. The Commission's Structural Theory and Presumption Are Unsupported by Economic Evidence**

The Commission argues mergers that reduce the number of competitors in a relevant market to three or two are unique in the sense that they warrant a presumption of competitive harm and illegality,[3] but it cannot defend its structural presumption upon the basis of economic evidence or accumulated empirical knowledge.

The Commission cites in support of its structural theory and presumption three academic articles written by economists.[4] Only two offer economic evidence, and the proffered substantiation fails to support the claim. The first is an important early entrant into the static entry literature examining the relationship between market size and the number of entrants in a market, focusing upon isolated rural markets.[5] It strains credulity to argue that Bresnahan and Reiss's important analysis of the impact of entry in markets involving doctors, dentists, druggists, plumbers, and tire dealers in local and isolated areas, where they find the competitive benefits of a second competitor are especially important, apply with generality sufficient to support a widely applicable presumption of harm based upon the number of firms. Indeed, the authors warn against precisely this interpretation of their work.[6]

The second article is a laboratory experiment and does not involve the behavior of actual firms and certainly cannot provide sufficient economic evidence to support a presumption that four-to-three and three-to-two mergers in real-world markets will result in anticompetitive coordination.[7] Once again, the authors warn against such an interpretation.[8]

Finally, the Commission cites a draft article, authored by Steve Salop, in support of its view that economic evidence supports a presumption that four-to-three and three-to-two mergers are competitively suspect.[9] The article does not purport to study or provide new economic evidence on the relationship between market structure and competition. Thus, it cannot

[1] As I explain below, I concur with the Commission as to the Twin Cities, Duluth, western Wisconsin, New Orleans, western Montana, Boston/Providence, the Mid-Atlantic region, and the western Great Lakes region; I dissent with the Commission as to eastern Iowa, Memphis, Baton Rouge, Detroit, northern Michigan, and Grand Rapids.

[2] *See* Analysis of Agreement Containing Consent Orders to Aid Public Comment 3, Holcim Ltd., FTC File No. 141–0129 (May 4, 2015) (''For many customers in these markets, the merger would . . . leav[e] the merged entity with the power to increase prices . . . unilaterally. Further, . . . it would enhance the likelihood of collusion or coordinated action between the remaining competitors.'').

[3] *Id.* at 3.

[4] *Id.* at 3 n.9.

[5] Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets,* 99 J. Pol. Econ. 977 (1991). While Bresnahan and Reiss is an important early contribution to the static entry literature, it cannot possibly bear the burden the Commission wishes to place upon it. Abstracting from the complexities of market definition was necessary for the researchers to isolate entry decisions. This is possible when studying the effects of entry by a second dentist in a town with a population of less than 1,000, but not in most real-world antitrust applications. The authors of the study make this point themselves, noting that ''whether this pattern appears in other industries remains an open question.'' *Id.* at 1007.

[6] In earlier research using similar empirical techniques and data—namely, small rural markets—Bresnahan and Reiss plainly reject the notion that the findings should inform views of market structure and competition generally: ''We do not believe that these markets 'stand in' for highly concentrated industries in the sectors of the economy where competition is national or global.'' Timothy F. Bresnahan & Peter C. Reiss, *Do Entry Conditions Vary Across Markets,* 3 Brookings Papers Econ. Activity 833, 868 (1987).

[7] Steffen Huck et al., *Two Are Few and Four Are Many: Number Effects from Experimental Oligopolies,* 53 J. Econ. Behavior & Org. 435 (2004).

[8] *Id.* at 436 (''The number of firms is not the only factor affecting competition in experimental markets. This implies that there exists no unique number of firms that determines a definite borderline between non-cooperative and collusive markets irrespective of all institutional and structural details of the experimental markets.'').

[9] Steven C. Salop, *The Evolution and Vitality of Merger Presumptions: A Decision-Theoretic Approach* (Georgetown Law Faculty Publications and Other Works, Working Paper No. 1304, 2014), *available at http://scholarship.law.georgetown.edu/facpub/1304/.*

support the Commission's proposition.[10]

There is simply no empirical economic evidence sufficient to warrant a *presumption* that anticompetitive coordination is likely to result from four-to-three or three-to-two mergers. Indeed, such a presumption would be inconsistent with modern economic theory and the analysis endorsed by the *Merger Guidelines,* which deemphasize inferences of competitive harm arising from market structure in favor of greater reliance upon particularized evidence of changes in post-merger incentives to compete.[11]

To the contrary, this approach is inconsistent with Agency practice and the letter and spirit of the more economically sophisticated approach adopted in the *Merger Guidelines.*[12] Section 2.1.3 of the *Merger Guidelines* does, as the Commission observes, state that ''mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power.'' [13] The *Merger Guidelines* insure against reverting to naked structural analysis by making clear that the role of market shares and market concentration is ''not an end in itself,'' but rather ''*one* useful indicator of likely anticompetitive effects,'' and that market concentration is not to be used to ''provide a rigid screen to separate competitively benign mergers from anticompetitive ones,'' but rather to provide one way to distinguish competitively benign mergers from *those that warrant closer scrutiny.*[14] To the extent these passages evince an ambiguity in the *Merger Guidelines* with respect to the minimum evidentiary burden that must be satisfied to support a merger challenge, the Commission should embrace the interpretation more consistent with a modern economic approach rather than with the obsolete and discredited structural analysis of a prior era.

Rather than relying upon economic evidence to defend the Commission's structural presumption, the Commission highlights case law supporting a presumption of illegality for mergers to duopoly or that substantially increase concentration.[15] As a preliminary matter, case law that endorses a wholly structural approach to merger analysis—an approach clearly rejected by the *Merger Guidelines*—does not constitute relevant economic evidence. Judicial opinions adopting this approach are orthogonal to the proposition in need of *economic substantiation:* that mergers resulting in three- or two-firm markets are likely to result in coordination. Indeed, one can find a variety of economically dubious propositions adopted in antitrust case law blessed by no less a legal authority than the Supreme Court.[16] But courts' observations about the relationship between market structure and competition are not relevant to the Commission's adoption of a structural presumption in this case.

I therefore find any reliance upon structural changes alone to be economically untenable and insufficient to give me reason to believe the proposed transaction will violate Section 7 in the vast majority of Relevant Markets.

## II. Coordinated Effects Are Unlikely in Any Relevant Market

The *Merger Guidelines* describe the conditions under which the antitrust agencies will challenge a proposed merger on the basis that it is likely to result in anticompetitive coordination. Specifically, the *Merger Guidelines* articulate three necessary conditions that must *each* be satisfied to support a coordinated effects theory: (1) A significant increase in concentration, leading to a moderately or highly concentrated market, (2) a market vulnerable to coordinated conduct, and (3) a credible basis for concluding the transaction will enhance that vulnerability.[17] Thus, the *Merger Guidelines* establish clearly that a highly concentrated market that is already vulnerable to coordinated conduct is necessary but not sufficient to support a coordinated effects theory. Critically, the Commission must also have evidence sufficient to provide a credible basis to conclude the transaction will *enhance* the market's vulnerability to coordinated conduct. Such evidence must evince a change in the post-merger competitive market dynamics and, in particular, post-merger incentives to engage in coordinated pricing. The *Merger Guidelines* provide the elimination of a maverick firm as an illustrative example of the type of evidence that would satisfy the third condition and warrant a presumption of adverse coordinated effects.[18] Importantly, the *Merger Guidelines* explain evidence that a merger will eliminate a maverick is given weight precisely because it

[10] Nevertheless, to the extent Salop argues in favor of legal presumptions in merger analysis, he clarifies that they ''obviously should be based on valid economic analysis, that is, proper economic presumptions,'' which should be updated ''based on new or additional economic factors besides market shares and concentration.'' *Id.* at 37, 48. I agree. Additionally, Salop explains that ''[c]ontemporary economic learning suggests that concentration be considered when undertaking competitive effects analysis—in conjunction with other factors suggested by the competitive effects theory—but not treated as the sole determinant of post-merger pricing.'' *Id.* at 13–14. Notably, Salop does not endorse a distinction between four-to-three mergers or three-to-two mergers and mergers in less concentrated markets that justifies a presumption that the former are anticompetitive; rather, he merely observes that empirical evidence and economic theory do not warrant ''*ignoring* market shares and concentration in merger analysis.'' *Id.* at 12 (emphasis in original).

[11] *See* Carl Shapiro, *The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years,* 77 Antitrust L.J. 701, 707–08 (2010) (acknowledging the role of market concentration in the analysis endorsed in the *Merger Guidelines* and observing that they place less weight upon market concentration and market shares, instead emphasizing the importance of direct evidence of changes in post-merger incentives to compete and competitive effects). To the extent the Commission relies upon Shapiro's caveat that ''changes in market concentration are more probative in some cases than others,'' Statement of the Federal Trade Commission 3 n.8, Holcim Ltd., FTC File No. 141–0129 (May 8, 2015), they fail to explain why, nor have I been provided any evidence attempting to establish that, markets for portland or slag concrete fit within the subset of cases for which it has been established that there is a reliable a relationship between market structure and competition. I do not quarrel with the notion that such markets exist. We identify them over time using economic analysis, empirical evidence, and accumulated learning. For example, substantial research has identified empirical regularities in the relationship between structure and price in generic pharmaceutical markets. *See* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics,* 87 Rev. Econ. & Stat. 37 (2005).

[12] Comments of the ABA Section of Antitrust Law on the Horizontal Merger Guidelines Revision Project (June 4, 2010), *available at https://www.ftc.gov/sites/default/files/documents/public_comments/horizontal-merger-guidelines-review-project-proposed-new-horizontal-merger-guidelines-548050-00026/548050-00026.pdf* (urging the agencies to ''remove the presumption of illegality keyed to the level and increase in the HHI'' because ''[t]he presumption does not reflect how the Agencies conduct investigations [and] is not theoretically warranted'').

[13] U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 7.1 (2010) [hereinafter Merger Guidelines].

[14] *Id.* §§ 4, 5.3.

[15] Statement of the Federal Trade Commission, *supra* note 11, at 3 (citing *Chicago Bridge & Iron Co.* v. *FTC,* 534 F.3d 410, 423 (5th Cir. 2008) and *FTC* v. *H.J. Heinz Co.,* 246 F.3d 708, 716 (D.C. Cir. 2001)).

[16] For example, well-established case law endorses the economic proposition that mergers that result in post-merger shares of greater than 30% are likely to harm competition, *United States* v. *Philadelphia Nat'l Bank,* 374 U.S. 321, 364–65 (1963), and that mergers resulting in post-merger shares of less than 10% harm competition when coupled with a trend toward concentration, *United States* v. *Von's Grocery Co.,* 384 U.S. 270 (1966); *United States* v. *Pabst Brewing Co.,* 384 U.S. 546 (1966).

[17] Merger Guidelines, *supra* note 13, § 7.1; *see also* Dissenting Statement of Commissioner Joshua D. Wright 3, Fidelity National Financial, Inc., FTC File No. 131–0159 (Dec. 23, 2013) [hereinafter Wright, *Fidelity Dissent*].

[18] Merger Guidelines, *supra* note 13, § 7.1.

changes post-merger incentives to coordinate.[19]

The first and second elements of the *Merger Guidelines'* coordinated effects analysis are not at issue in this case. The Commission's investigation revealed evidence supporting a conclusion that the Relevant Markets are already highly concentrated and the proposed transaction will increase concentration.[20] Furthermore, the evidence supports a conclusion that the markets are vulnerable to coordinated conduct.[21] Nevertheless, the investigation failed to uncover any evidence to suggest the proposed transaction will increase post-merger incentives to coordinate—that is, there is no record evidence to provide a credible basis to conclude the merger alters the competitive dynamic in any Relevant Market in a manner that enhances its vulnerability to coordinated conduct.

The Commission asserts that the facts that the market is highly concentrated, that it is vulnerable to coordination, and that the merger reduces ''the number of significant competitors to only two or three'' [22] jointly satisfy the third necessary element that ''the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability.''[23] The Commission's analysis can be read in one of two ways. Each is tantamount to the application of a structural presumption for coordinated effects claims involving markets with three or two firms, each is problematic because it adopts an outdated and obsolete structural approach to coordinated effects, and each is in significant tension with the economic approach to coordinated effects embodied in the *Merger Guidelines.*

The first interpretation is that the satisfaction of the first and second elements of the *Merger Guidelines* analysis—and particularly the demonstration that the merger significantly increases concentration in an already concentrated market—is sufficient to simultaneously satisfy the third element that the merger enhance post-merger incentives to coordinate. This interpretation renders the third element of Section 7.1 entirely superfluous. The more logical explanation of the third element is that a crucial, additional type of information is required to illuminate how the merger changes the merged firm's incentives to coordinate. The Commission's application completely overlooks the economic relevance of the third element.

The second plausible interpretation of the Commission's analysis is that the reduction in the number of competitors in a market is itself sufficient evidence to provide a credible basis that a merger will enhance a market's vulnerability to coordination and thus satisfy the third element of the *Merger Guidelines'* coordinated effects analysis. Under this reading, the Commission relies upon the fact that the proposed transaction reduces the number of competitors in each Relevant Market by one firm, either from four to three or from three to two.[24] For example, the Majority Statement asserts that the proposed transaction might enhance the likelihood of coordination by ''mak[ing] it easier for the remaining firms to coordinate, monitor compliance with, and retaliate against potential deviation from, a coordinated scheme.'' [25] These are generic observations that are true of any merger that reduces the number of firms in a market; they are not particularized to the proposed transaction or to any Relevant Market nor do they establish a credible basis to conclude that post-merger incentives to coordinate will increase. The observation that a market with N firms will, after the merger, have N–1 firms is simply insufficient without more to establish the required credible basis. This is true even when a merger reduces the number of firms from four to three or from three to two. The Commission offers no explanation as to why the *Merger Guidelines* would go through the trouble of requiring a credible basis to believe a merger will change the market's competitive dynamics that *enhances* the market's vulnerability to coordinated conduct, *in addition to* an increase in market concentration, in order to substantiate a coordinated effects merger challenge if the latter were considered sufficient to satisfy both elements.

As I have stated previously, ''there is no basis in modern economics to conclude with any modicum of reliability that increased concentration—without more—will increase post-merger incentives to coordinate.'' [26] Janusz Ordover, in a leading treatment of the economics of coordinated effects, similarly explains that ''[i]t is now well understood that it is not sufficient when gauging the likelihood of coordinated effects from a merger to simply observe that because the merger reduces the number of firms, it automatically lessens the coordination problem facing the firms and enhances their incentives to engage in tacit collusion; far from it.''[27] Without particularized evidence that the proposed transaction will enhance incentives to coordinate post-merger, I am unable to conclude there is reason to believe it is likely to substantially lessen competition in violation of Section 7.

### III. Unilateral Effects Are Unlikely in Some of the Relevant Markets

The Commission alleges the proposed transaction is likely to result in unilateral price effects in the Relevant Markets. Unilateral effects arise when the reduction in direct competition between merging firms is sufficient to create post-merger market power. The *Merger Guidelines* articulate a variety of potential unilateral effects theories, including merger to monopoly, merger of firms producing very close substitutes in a differentiated products market, merger of sellers competing in bargaining and auction markets, and mergers in homogeneous goods markets making post-merger output suppression strategies more profitable.[28] The unifying theme of the unilateral effects analysis contemplated by the *Merger Guidelines* is that a particularized showing that post-merger competitive constraints are weakened or eliminated by the merger is superior to relying solely upon inferences of competitive effects drawn from changes in market structure.[29]

The potential unilateral effects theories in this case fall broadly within one of three categories. The first category involves straightforward merger-to-monopoly markets. In these markets, the theory of harm is that Holcim and Lafarge are the only two meaningful suppliers for all customers in the Relevant Market. The second

[19] *Id.* § 2.1.5.

[20] *See* Analysis of Agreement Containing Consent Orders to Aid Public Comment, *supra* note 2, at 2.

[21] *See* Statement of the Federal Trade Commission, *supra* note 11, at 2 (describing the characteristics of the Relevant Markets that render them vulnerable to coordination).

[22] *Id.* at 2.

[23] Merger Guidelines, *supra* note 13, § 7.1.

[24] *See* Statement of the Federal Trade Commission, *supra* note 11, at 2 (taking the view that a reduction of competitors to three or two firms in the relevant market justify a presumption of competitive harm).

[25] *Id.* at 2.

[26] Wright, *Fidelity Dissent, supra* note 17, at 3.

[27] Janusz A. Ordover, *Coordinated Effects, in* 2 Issues in Competition Law and Policy 1359, 1367 (ABA Section of Antitrust Law 2008) (''It is quite clear . . . that a reduction in the number of firms and concomitant increases in concentration do not necessarily make collusion inevitable or even more likely, stable, or complete.'').

[28] Merger Guidelines, *supra* note 13, § 6.

[29] *See* Shapiro, *supra* note 11, Part III (explaining the *Merger Guidelines'* unilateral effects analysis, the types of evidence that support such analysis, and the relative analytical weakness of inferences of competitive harm drawn from changes in market structure).

category involves markets in which Holcim and Lafarge face some competition, but the proposed transaction will result in a merger to monopoly for a substantial subset of customers and will allow the merged entity to unilaterally increase market prices. The third category includes markets where the proposed transaction will reduce the number of competitors in the Relevant Market to three or two, and the remaining competitors will be unable or unwilling to compete for market share—for example, because of capacity constraints, leaving the merged entity with the ability to unilaterally raise prices. Each of these theories requires particularized evidence sufficient to establish reason to believe the proposed transaction violates Section 7 of the Clayton Act. I conclude the available evidence is sufficient to do so in some Relevant Markets and insufficient in others.

Unilateral price effects are ''most apparent in a merger to monopoly in a relevant market.'' [30] Basic economic theory provides a robust and reliable inference that a merger to monopoly or near monopoly is likely to result in anticompetitive effects. A rational firm with little or no competitive constraints will set prices or choose output to maximize its profits; it can be expected that a rational firm acquiring such monopoly power will adjust prices and output accordingly. No further economic evidence is required to substantiate an enforcement action based upon likely unilateral price effects and to establish reason to believe a merger to monopoly or near monopoly is likely to violate Section 7 of the Clayton Act. This analysis applies to at least one of the Relevant Markets.

The analysis is necessarily more nuanced for theories falling within the second category of theories of unilateral price effects. These theories involve Relevant Markets where the proposed transaction would reduce the number of competitors from four to three or three to two, and the market share for the merged entity would not be large enough to infer it would have the power to raise market prices unilaterally. In these markets, particularized evidence is required to establish reason to believe the merged firm will gain unilateral pricing power. In many Relevant Markets, staff was successful in uncovering the required evidence. For example, in some Relevant Markets, there was evidence of a significant subset of customers for whom a sole market participant would be the only remaining acceptable supplier, due either to physical proximity or to some other preference rendering alternatives an unacceptable source of portland or slag cement. The Commission's example of ready-mix concrete producers,[31] a relevant subset of customers, is an illustrative example here. In some Relevant Markets, the evidence supports a finding that such customers would continue to find their vertically integrated rivals to be an unacceptable source of portland cement, even if the sole remaining vertically unintegrated portland cement producer raised its prices after the merger. In the Relevant Markets for which credible evidence of this type is available, I find it sufficient to create reason to believe the merger is likely to result in competitive harm. Several other Relevant Markets fall into this category.

In other Relevant Markets, the allegation that there will remain only one acceptable supplier for a significant subset of customers after the proposed transaction lacks evidentiary support. Specifically, in these markets, the record evidence does not indicate that a material number of customers view Holcim and Lafarge as closest supply alternatives or that they view other potential suppliers as unacceptable supply sources and would continue to do so in the face of a post-merger unilateral price increase.[32]

The final category of potential unilateral effects theories, like the second category, also involves Relevant Markets where the proposed transaction would reduce the number of competitors from four to three or three to two, but the post-merger market share would not be large enough to infer it would have the power to raise market prices unilaterally. However, unlike the second category, in these Relevant Markets, it is not customer preference that limits the number of available competitors to one. Rather, in these Relevant Markets, the proposed transaction is effectively a merger to monopoly or near monopoly because alternative suppliers would be unwilling or unable to compete with the merged entity in the face of a price increase. In some Relevant Markets, the investigation uncovered particularized evidence sufficient to establish a reason to believe such unilateral effects are likely, including evidence that other competitors are experiencing, or soon will experience, capacity constraints, rendering them unable or unwilling to compete for market share, or that other suppliers will not constrain the merged entity's prices. Several Relevant Markets fall into this third category.

Relevant Markets where the ''reason to believe'' standard is not satisfied lacked record evidence necessary to corroborate any of these three theories.[33] Indeed, with respect to the Relevant Markets for which I dissent from the Commission's decision, it is my view that the investigation failed to adduce particularized evidence to elevate the anticipated likelihood of competitive effects from ''possible'' to ''likely'' under any of these theories. Without this necessary evidence, the only remaining factual basis upon which the Commission rests its decision is the fact that the merger will reduce the number of competitors from four to three or three to two. This is simply not enough evidence to support a reason to believe the proposed transaction will violate the Clayton Act in these Relevant Markets.

## IV. Conclusion

Prior to entering into a consent agreement with the merging parties, the Commission must first find reason to believe that a merger likely will substantially lessen competition under Section 7 of the Clayton Act. A presumption that such reason to believe exists when a merger decreases in the number of competitors in a market to three or two is misguided. Additionally, when the Commission alleges coordinated or unilateral effects arising from a proposed transaction, this standard requires more than a mere counting of pre- and post-merger firms. In particular, reason to believe a proposed transaction is likely to result in coordinated effects requires evidence—absent from the record here—that the merger will *enhance* a market's vulnerability to coordinated pricing, and not just that it takes place in a market that is already concentrated. In the absence of such a particularized showing, the Commission's approach to coordinated effects here reduces to a strict structural presumption

[30] Merger Guidelines, *supra* note 13, § 6.

[31] *See* Statement of the Federal Trade Commission, *supra* note 11, at 2 n.5.

[32] The role of ready-mix customers in the competitive analysis is again illustrative. In some Relevant Markets the available evidence indicates there are some ready-mix customers that purchase from rivals and others that do not, but the totality of the evidence fails to establish the existence of a significant set of customers that view vertically integrated suppliers as unacceptable or would continue to do so in the face of a post-merger unilateral price increase.

[33] One other potentially plausible theory is that customers refuse to sole source their product, and therefore that two or more competitors are necessary to prevent post-merger unilateral effects. There is insufficient record evidence to indicate customers would be unwilling to switch from dual- to single-sourced supply in the event of a post-merger price increase.

unsupported by modern economics and at odds with the *Merger Guidelines.*

Similarly, substantiating a unilateral effects theory requires particularized evidence—also absent from the record here in some Relevant Markets—that a merger will reduce or eliminate competitive constraints, permitting the merged entity to increase prices. Without such evidence, a unilateral effects theory reduces to little more than a complaint about market structure coupled with speculation about the circumstances under which unilateral effects might occur in a post-merger world. The *Merger Guidelines* contemplate a more rigorous analysis.

This is not to suggest the ''reason to believe'' standard requires access to every piece of relevant information and a full and complete economic analysis of a proposed transaction, regardless of whether the parties wish to propose divestitures before complying with a Second Request. Rather, the standard requires only evidence sufficient to establish that competitive harm is likely. Such evidence, although quite minimal—indeed, a handful of facts in most instances—is indeed available in some Relevant Markets in this matter, and it is in those markets that I concur with the Commission's decision. While I appreciate the practical complications of requesting additional information during the course of a merger investigation, as well as the desire to conduct efficient investigations, these important pragmatic considerations do not trump the Commission's primary obligation to collect evidence sufficient to establish reason to believe the merger will harm competition before issuing a complaint and accepting a consent.

For the reasons I explain above, I find reason to believe the proposed transaction is likely to result in unilateral price effects, and thus violate the Clayton Act, in the Twin Cities, Duluth, western Wisconsin, New Orleans, western Montana, Boston/Providence, the Mid-Atlantic region, and the western Great Lakes region. I conclude there is no reason to believe the proposed transaction will violate Section 7 in eastern Iowa, Memphis, Baton Rouge, Detroit, northern Michigan, and Grand Rapids; it follows that I believe the Commission should refrain from imposing a remedy in these markets.

[FR Doc. 2015–11724 Filed 5–14–15; 8:45 am]

BILLING CODE 6750–01–P

## GENERAL SERVICES ADMINISTRATION

**[OMB Control No. 3090–0205; Docket 2015–0001; Sequence 12]**

## General Services Administration Acquisition Regulation (GSAR; Information Collection; Environmental Conservation, Occupational Safety, and Drug-Free Workplace

**AGENCY:** Office of Acquisition Policy, General Services Administration (GSA).

**ACTION:** Notice of request for comments regarding the extension of a previously existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding Environmental Conservation, Occupational Safety, and Drug-Free Workplace.

**DATES:** Submit comments on or before: July 14, 2015.

**ADDRESSES:** Submit comments identified by Information Collection 3090–02085 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace'' on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace.

*Instructions:* Please submit comments only and cite Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

**FOR FURTHER INFORMATION CONTACT:** Kevin Funk, Procurement Analyst, General Services Acquisition Policy Division, GSA, at telephone 215–446–4860 or via email to *kevin.funk@gsa.gov.*

**SUPPLEMENTARY INFORMATION:**

### A. Purpose

The Federal Hazardous Substance Act and Hazardous Material Transportation Act prescribe standards for packaging of hazardous substances. To meet the requirements of the Acts, the General Services Administration Regulation prescribes provision 552.223–72, Hazardous Material Information, to be inserted in solicitations and contracts that provides for delivery of hazardous materials on an f.o.b. origin basis.

This information collection will be accomplished by means of the provision which requires the contractor to identify for each National Stock Number, the DOT Shipping Name, DOT Hazards Class, and whether the item requires a DOT label. Contracting Officers and technical personnel use the information to monitor and ensure contract requirements based on law and regulation.

Properly identified and labeled items of hazardous material allows for appropriate handling of such items throughout GSA's supply chain system. The information is used by GSA, stored in an NSN database and provided to GSA customers. Non-Collection and/or a less frequently conducted collection of the information resulting from provision 552.223–72 would prevent the Government from being properly notified. Government activities may be hindered from apprising their employees of; (1) All hazards to which they may be exposed; (2) Relative symptoms and appropriate emergency treatment; and (3) Proper conditions and precautions for safe use and exposure.

### B. Annual Reporting Burden

*Respondents:* 563.
*Responses per Respondent:* 3.
*Total Responses:* 1689.
*Hours per Response:* .67.
*Total Burden Hours:* 1132.

### C. Public Comments

Public Comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

*Obtaining Copies of Proposals:* Requesters may obtain a copy of the

information collection documents from the General Services Administration, Regulatory Secretariat Division, 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence.

Dated: May 12, 2015.

**Jeffrey A Koses,**

*Director, Office of Acquisition Policy, Senior Procurement Executive.*

[FR Doc. 2015–11749 Filed 5–14–15; 8:45 am]

**BILLING CODE 6820–61–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–437A & CMS–437B]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by July 14, 2015.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS–437A & CMS–437B State Agency Sheets for Verifying Exclusions From the Inpatient Prospective Payment System and Supporting Regulations**

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations *Use:* For first time verification requests for exclusion from the Inpatient Prospective Payment System (IPPS), a hospital/unit must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new inpatient rehabilitation facilities (IRFs) must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. They must also complete the Form CMS–437A if they are a rehabilitation unit or complete Form CMS–437B if they are a rehabilitation hospital. This information is submitted to the State Agency (SA) no later than 5 months before the date the hospital/unit would become subject to IRF–PPS.

We propose to continue to use the Criteria Worksheets (Forms CMS–437A and CMS–437B) for verifying first-time exclusions from the IPPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the IPPS-excluded rehabilitation units and rehabilitation hospitals.

For rehabilitation hospitals and rehabilitation units already excluded from the IPPS, annual onsite re-verification surveys by the SA are not required. These hospitals and units will be provided with a copy of the appropriate CMS–437 Worksheet at least 5-months prior to the beginning of its cost reporting period, so that the hospital/unit official may complete and sign an attestation statement and complete and return the appropriate CMS–437A or CMS–437B at least 5-months prior to the beginning of its cost reporting period. Fiscal Intermediaries will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement.

The SA will maintain the documents unless instructed otherwise by the RO.

The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period of the IRF's compliance or non-compliance with the payment requirements. The information collected on these forms, along with other information submitted by the IRF is necessary for determining exclusion from the IPPS. Hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria.

*Form Number:* CMS–437A and CMS–437B (OMB Control Number: 0938–0986); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 478; *Total Annual Responses:* 478; *Total Annual Hours:* 120. (For policy questions regarding this collection contact James Cowher at 410–786–1948).

Dated: May 12, 2015.

**William N. Parham, III**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015–11798 Filed 5–14–15; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–1484]**

### Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist sponsor-investigators in preparing and submitting complete investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at FDA. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. Details of the informational content of an IND as well as information needed to complete required forms also are provided throughout this guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 14, 2015.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6439, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist investigators in preparing and submitting complete INDs to CDER and CBER at FDA. Sponsor-investigators seeking to do clinical research often do not have the regulatory knowledge or the resources to hire experts to help them with the IND submission process. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. The guidance does not include discussions of all of the requirements that apply to the IND submission and review process or to conducting clinical research.

This guidance is directed primarily at those sponsor-investigators who are seeking to evaluate a drug that is either currently approved or is being investigated under an existing IND for a different indication. This guidance is not intended for sponsor-investigators who are developing a drug for commercial purposes (*i.e.,* seeking market approval or licensure). This guidance does not apply to clinical trials that do not need to be conducted under an IND (*i.e.,* that qualify for an IND exemption). The guidance also is not intended to address expanded access INDs or biologic devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on INDs prepared and submitted by sponsor-investigators. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

#### II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 312 have been approved under OMB control number 0910–0014.

#### III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and

will be posted to the docket at *http://www.regulations.gov.*

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: May 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–11685 Filed 5–14–15; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Food and Drug Administration-American Urological Association-Society of Urologic Oncology Workshop on Partial Gland Ablation for Prostate Cancer; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''AUA–FDA–SUO Workshop on Partial Gland Ablation for Prostate Cancer.'' The topics to be discussed are the technologies and imaging used in partial gland ablation, and the design of clinical trials to measure the most appropriate endpoints for partial gland ablation for prostate cancer. The workshop will be part of the American Urological Association (AUA) annual meeting in New Orleans, LA.

**DATES:** The public workshop will be held on Sunday, May 17, 2015, from 1 p.m. to 6 p.m.

**ADDRESSES:** The workshop will be held at the New Orleans Ernest N. Morial Convention Center, 900 Convention Center Blvd., New Orleans, LA 70130.

*Registration:* Persons interested in attending this workshop must register online for the AUA annual meeting. The facilities are limited and, therefore, attendance may be limited. To register for the workshop, please visit the AUA Web site, *http://www.aua2015.org/register/.*

If you need special accommodations due to a disability, please contact Ms. Susan Monahan, 301–796–5661, email: *susan.monahan@fda.hhs.gov.*

For more information on the workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this workshop from the posted events list.) No commercial or promotional material will be permitted to be presented or distributed at the workshop.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management between 9 a.m. and 4 p.m. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this workshop from the posted events list), approximately 45 days after the workshop.

**FOR FURTHER INFORMATION CONTACT:** John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993, 301–796–6549, email: *john.baxley@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA's Center for Devices and Radiological Health, the AUA, and the Society of Urologic Oncology (SUO) are cosponsoring this workshop. The purpose is to provide a forum to discuss the development of products that ablate prostatic tissue, particularly products that target ablation to regions of known cancer while intentionally sparing the remainder of the prostate from treatment.

The majority of cases of prostate cancer diagnosed in the United States represent low risk, organ-confined disease, which may be overtreated if conventional treatment methods (*i.e.,* radical prostatectomy and whole gland radiation therapy) are employed. Over the past decade, partial gland ablation therapies have emerged as treatment alternatives that can spare patients from many of the undesired side effects associated with standard, radical treatment. However, multiple challenges currently impede the adoption of partial gland ablation technologies, including the long natural history associated with this disease, imprecision in accurately diagnosing and targeting the tumor regions, and the lack of validated biomarkers or surrogate endpoints to establish clinical benefit in a reasonable period of time.

The purposes of this public workshop are to: (1) Foster collaboration and receive input from experts within the scientific community; (2) obtain input from various stakeholders including patients, investigators and industry regarding the development of minimally invasive devices to ablate prostatic tissue; (3) foster clinical research; (4) discuss strategies to accelerate anticancer device development; and (5) provide transparency via a public forum regarding the regulatory challenges of developing products for management of patients with localized prostate cancer.

**II. Topics for Discussion at the Public Workshop**

The following topics will be discussed at this workshop:

- Regulatory issues in partial gland ablation for prostate cancer;
- overview of technology and consensus reports;
- the use of imaging and biopsy for patient selection and treatment targeting; and
- the design of clinical trials to measure cancer-specific and patient-centered outcomes.

The workshop will consist of formal presentations examining these regulatory, scientific and clinical topics, followed by panel discussion. During panel discussion, there will also be the opportunity for public participation and input.

Dated: May 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–11897 Filed 5–13–15; 11:15 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–1211]**

### Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing the availability of a draft document entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry.'' The draft guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with revised donor deferral recommendations for individuals at increased risk for transmitting human immunodeficiency virus (HIV) infection. The draft guidance document recommends corresponding revisions to donor education materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures. The document also incorporates certain other recommendations related to donor education materials and testing contained in the memorandum to blood establishments entitled, ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,'' dated April 23, 1992 (1992 blood memo). The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 14, 2015.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft document entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry.'' The emergence of Acquired Immune Deficiency Syndrome (AIDS) in the early 1980s and the recognition that it could be transmitted by blood and blood products had profound effects on the U.S. blood system. Although initially identified in men who have sex with men (MSM) and associated with male-to-male sexual contact, AIDS was soon noted to be potentially transmitted by transfusion of blood components, and by infusion of clotting factor concentrates in individuals with hemophilia. Beginning in 1983, the FDA, issued recommendations for providing donors with education material on risk factors for AIDS and for deferring donors with such risk factors in an effort to prevent transmission of AIDS (later understood to be caused by HIV) by blood and blood products.

Since September 1985, FDA has recommended that blood establishments indefinitely defer male donors who have had sex with another male, even one time, since 1977, due to the strong clustering of AIDS illness in the MSM community and the subsequent discovery of high rates of HIV infection in that population. On April 23, 1992, FDA issued the 1992 blood memo, which contains the current recommendations regarding the deferral for MSM, as well as the deferral recommendations for other persons with behaviors associated with high rates of HIV exposure, namely commercial sex workers, intravenous drug users, and certain other individuals with other risk factors.

The use of donor education material, specific deferral questions and advances in HIV donor testing have reduced the risk of HIV transmission from blood transfusion from about 1 in 2500 units prior to HIV testing to a current estimated residual risk of about 1 in 1.47 million transfusions. During the period from 1997 to 2014, FDA and the Department of Health and Human Services (HHS) held a number of public meetings, including scientific workshops and meetings of the Blood Products Advisory Committee and the HHS Advisory Committee on Blood Safety and Availability to further review evidence and discuss FDA's blood donor deferral policies to reduce the risk of transmission of HIV by blood and blood products. Studies that might support a policy change were carried out by the Public Health Service agencies in 2011–2014. A policy change to the blood donor deferral period for MSM from indefinite deferral to 1 year since the last sexual contact was announced by the FDA Commissioner in December 2014. The draft guidance, when finalized, will implement that policy change.

In addition to providing donor deferral recommendations for individuals at increased risk for transmitting HIV infection, the draft guidance document incorporates certain recommendations contained in the 1992 blood memo. Certain other recommendations from the 1992 blood memo have not been included in the draft guidance document because they have become outdated over time, superseded by subsequent regulations or guidance documents, or have been incorporated into other guidance documents. However, to ensure that the final guidance document provides comprehensive recommendations for reducing the risk of HIV transmission by blood and blood products, we invite comments on the recommendations contained in the 1992 blood memo that have not been included in the draft guidance. Further, the draft guidance does not provide a specific list of recommended signs and symptoms associated with HIV for inclusion in the donor education materials. We invite comments and the submission of data on what specific signs and symptoms associated with HIV infection would be most appropriate for inclusion in education material in the blood donor setting. The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

The draft guidance 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 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458; and the collections of information in 21 CFR 610.46, 630.6, 640.3 and 640.63 have been approved under OMB control number 0910–0116.

**III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–11690 Filed 5–14–15; 8:45 am]

**BILLING CODE 4164–01–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0487]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** On September 24, 2014, the Agency submitted a proposed collection of information entitled, ''Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery'' 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 0910–0697. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–11689 Filed 5–14–15; 8:45 am]

**BILLING CODE 4164–01–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### U.S. National Authority for the WHO Global Code of Practice on the International Recruitment of Health Personnel; Notice of Public Meeting

*Time and date:* Meeting will be held on June 10th, 2015, 10:00 a.m. to 12:00 p.m. EDT.

*Place:* Room 405A, U.S. Department of Health & Human Services, 200 Independence Ave. SW., Washington, DC 20201.

*Status:* Open, but requiring RSVP to *us.who.irhp@hhs.gov* by June 3rd, 2015.

*Purpose:* The purpose of the World Health Organization (WHO) Global Code of Practice on International Recruitment of Health Personnel (Global Code) is ''to establish and promote voluntary principles and practices for the ethical international recruitment of health personnel and to facilitate the strengthening of health systems.'' The United States Government has designated the Office of Global Affairs (OGA) and the Health Resources and Services Administration (HRSA) as co-National Authority to be the point of contact for implementation activities. The Global Code encourages WHO member states to cooperate with all relevant stakeholders in their implementation efforts. This meeting is thus intended to provide an update to all interested stakeholders on U.S. Global Code implementation efforts to date and to provide a forum for questions on activities related to implementation of the Global Code.

The meeting will be open to the public as indicated above, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify within their RSVP at least 10 business days prior to the meeting. Foreign nationals planning to attend the session in person will require additional paperwork for security clearance and that this clearance process requires a minimum of 10 business days.

*RSVP:* Due to security restrictions for entry into the HHS Humphrey Federal Building, we will need to receive RSVPs for this event. Please send your full name and organization to *us.who.irhp@hhs.gov.* If you are *not* a U.S. citizen, you must RSVP no later than May 26th, 2015. Please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information for your clearance. For U.S. citizens, please RSVP no later than Friday, June 3rd, 2015. Written comments are welcome and encouraged, even if you are planning to attend in person. Please send these to the email address: *us.who.irhp@hhs.gov.*

Dated: May 7, 2015.

**Jimmy Kolker,**

*Assistant Secretary for Global Affairs, Department of Health and Human Services.*

[FR Doc. 2015–11785 Filed 5–14–15; 8:45 am]

**BILLING CODE 4150–38–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Behavioral Genetics and Epidemiology.

*Date:* June 2–3, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

*Contact Person:* George Vogler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, MSC 7770, Bethesda, MD 20892, (301) 237–2693, *voglergp@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Innate Immunity and Inflammation.

*Date:* June 5, 2015.

*Time:* 1:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* JW Marriott, 614 Canal Street, New Orleans, LA 70130.

*Contact Person:* Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–594–6375, *mcintyrt@csr.nih.gov.*

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Clinical Oncology Study Section.

*Date:* June 8, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Le Méridien Delfina Santa Monica, 530 Pico Blvd., Santa Monica, CA 90405.

*Contact Person:* Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301–806–2515, *chatterm@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Macromolecular Structure and Function.

*Date:* June 10, 2015.

*Time:* 8:00 a.m. to 10:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301)451–1323, *assamunu@csr.nih.gov.*

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

*Contact Person:* Priscah Mujuru, DRPH, BSN, COHNS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *mujurup@mail.nih.gov.*

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

*Date:* June 11, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Martha Garcia, Ph.D., Scientific Reviewer Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, Bethesda, MD 20892, 301–435–1243, *garciamc@nih.gov.*

*Name of Committee:* Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Seattle Hotel, 1400 6th Avenue, Seattle, WA 98101.

*Contact Person:* Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov.*

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiac Contractility, Hypertrophy, and Failure Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Warwick Seattle Hotel, 401 Lenora Street, Seattle, WA 98121.

*Contact Person:* Olga A. Tjurmina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4030B, MSC 7814, Bethesda, MD 20892, (301) 451–1375, *ot3d@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA–RM–14–004: NIH Director's Early Independence Awards Review.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

*Contact Person:* Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, (301) 594–3292, *niw@csr.nih.gov.*

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Respiratory Integrative Biology and Translational Research Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

*Contact Person:* Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.nih.gov.*

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

*Contact Person:* Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov.*

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

*Contact Person:* Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Torrance Marriot South Bay, 3635 Fashion Way, Torrance, CA 90503.

*Contact Person:* Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Learning and Memory Study Section.

*Date:* June 11, 2015.

*Time:* 8:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

*Contact Person:* Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 5181 MSC 7846, Bethesda, MD 20892–7846, 301–435–1236, *zhaow@csr.nih.gov.*

*Name of Committee:* Cell Biology Integrated Review Group; Biology of the Visual System Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

*Contact Person:* Michael H. Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435–0910, *chaitinm@csr.nih.gov*.

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

*Contact Person:* Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–1721, *hfriedman@csr.nih.gov*.

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry A Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Seattle Hotel, 1400 6th Ave., Seattle, WA 98101.

*Contact Person:* Mike Radtke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301–435–1728, *radtkem@csr.nih.gov*.

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Kinzie Hotel, 20 W Kinzie St, Chicago, IL 60654.

*Contact Person:* William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov*.

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

*Date:* June 11, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

*Date:* June 11, 2015.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 2620 Hotel Fisherman's Wharf, 2620 Jones Street, San Francisco, CA 94133.

*Contact Person:* Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov*.

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov*.

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301–435–2204, *girouxcn@csr.nih.gov*.

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Health Disparities and Equity Promotion Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

*Contact Person:* Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–0684, *olufokunbisamd@csr.nih.gov*.

*Name of Committee:* Immunology Integrated Review Group; Immunity and Host Defense Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–435–1506, *jakesse@mail.nih.gov*.

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Medical Imaging Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* Grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov*.

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Molecular Imaging and Probe Development.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* David L. Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301) 435–1174, *williamsdl2@csr.nih.gov*.

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

*Date:* June 11–12, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

*Contact Person:* Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, (301) 594–3163, *champoum@csr.nih.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Mobile Health: Technology and Outcomes in Low and Middle Income Countries.

*Date:*June 11–12, 2015.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Social Psychology, Personality and Interpersonal Processes.

*Date:* June 12, 2015.

*Time:* 10:30 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

*Contact Person:* Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Development and Application of PET and SPECT Imaging Ligands as Biomarkers for Drug Discovery and for Pathophysiological Studies of CNS Disorders (R21).

*Date:* June 12, 2015.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* David L. Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301)435–1174, *williamsdl2@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11717 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Career Development Program to Promote Diversity in Health Research.

*Date:* June 8, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11712 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Allergy, Immunology, and Transplantation Research Committee.

*Date:* June 16, 2015.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5601 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/NIAID, National Institutes of Health, 5601 Fishers Lane, 3G31B, Bethesda, MD 20892, 240–669–5060, *james.snyder@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 11, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11708 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* June 11, 2015.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Sherry L. Dupere, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 451–3415, *duperes@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11711 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), notice is hereby given of the Joint meeting of the National Cancer Advisory Board (NCAB) and NCI Board of Scientific Advisors (BSA).

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Advisory Board *Ad Hoc* Subcommittee on Global Cancer Research.

Open: June 23, 2015, 6:30 p.m. to 8:00 p.m.

*Agenda:* Discussion on Global Cancer Research.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Edward L. Trimble, M.D., Executive Secretary, NCAB *Ad Hoc* Subcommittee on Global Cancer Research, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, Room 3W562, Bethesda, MD 20892, (240) 276–5796, *trimblet@mail.nih.gov.*

*Name of Committee:* National Cancer Advisory Board and NCI Board of Scientific Advisors.

Open: June 24, 2015, 9:00 a.m. to 4:00 p.m.

*Agenda:* Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors; NCI Board of Scientific Advisors Concepts Review, NCI Director's report, and presentations.

Closed: June 24, 2015, 4:00 p.m. to 5:30 p.m.

*Agenda:* Review of NCAB grant applications.

*Place:* National Institutes of Health, Building 31, C-Wing, 6th Floor, Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCAB: *http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm,* or BSA: *http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11704 Filed 5–14–15; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, June 10, 2015, 09:15 a.m. to June 10, 2015, 04:00 p.m., National Institutes of Health, 5635 Fishers Lane, Terrace Conference Rooms, Bethesda, MD 20892 which was published in the **Federal Register** on May 05, 2015, 80 FR 25703.

This notice is being amended to change the start times of the closed session from 9:15 a.m. to 9:00 a.m. and the open session from 11:00 a.m. to 10:15 a.m. on June 10, 2015. The meeting is partially closed to the public.

Dated: May 11, 2015.

**Melanie J. Gray-Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11706 Filed 5–14–15; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Risk, Prevention and Intervention for Addictions.

*Date:* June 4, 2015.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Circle Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, (301) 594–3292, *niw@csr.nih.gov.*

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Dissemination and Implementation Research in Health Study Section.

*Date:* June 8–9, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, 7400 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* Martha L. Hare, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular and Hematology.

*Date:* June 10, 2015.

*Time:* 2:00 p.m. to 4:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
*Contact Person:* Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov*.

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.
*Date:* June 11–12, 2015.
*Time:* 8:00 a.m. to 5:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.
*Contact Person:* C-L- Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, 301–435–1016, *wangca@csr.nih.gov*.

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurotransporters, Receptors, and Calcium Signaling Study Section.
*Date:* June 11, 2015.
*Time:* 8:00 a.m. to 7:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Hotel Palomar, 2121 P Street NW., Washington, DC 20037.
*Contact Person:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Investigations on Primary Immunodeficiency Diseases.
*Date:* June 11, 2015.
*Time:* 1:00 p.m. to 4:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
*Contact Person:* Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov*.

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.
*Date:* June 15–16, 2015.
*Time:* 8:00 a.m. to 12:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.
*Contact Person:* Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov*.

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.
*Date:* June 15–16, 2015.
*Time:* 8:00 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Lord Baltimore Hotel, 20 West Baltimore St., Baltimore, MD 21201.
*Contact Person:* Daniel F. McDonald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov*.

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.
*Date:* June 15–16, 2015.
*Time:* 8:00 a.m. to 1:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.
*Contact Person:* Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7770, Bethesda, MD 20892, (301) 455–1761, kellya2@csr.nih.gov.

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.
*Date:* June 15, 2015.
*Time:* 8:00 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.
*Contact Person:* Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov*.

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section.
*Date:* June 15–16, 2015.
*Time:* 8:00 a.m. to 5:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* The Westin Riverwalk Hotel, 420 West Market Street, San Antonio, TX 78205.
*Contact Person:* Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov*.

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Bacterial Pathogenesis Study Section.
*Date:* June 15–16, 2015.
*Time:* 8:30 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Embassy Suites Alexandria-Old Town, 1900 Diagonal Road, Alexandria, VA 22314.
*Contact Person:* Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, *marci.scidmore@nih.gov*.

*Name of Committee:* Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.
*Date:* June 16, 2015.
*Time:* 8:00 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.
*Contact Person:* Bukhtiar H. Shah, Ph.D., DVM, Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).
*Date:* June 16–17, 2015.
*Time:* 8:00 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
*Contact Person:* Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414, *huzhuang@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11702 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

*Date*: June 8, 2015.

*Time:* 10:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G41B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC9823, Bethesda, MD 20892–9823, (240) 669–5068, *zhuqing.li@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 11, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11709 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* June 30, 2015.

*Time:* 3:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11710 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Secondary data analysis R03 review.

*Date:* June 9, 2015.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

*Contact Person:* Jayalakshmi Raman, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, One Democracy Plaza, Room 670, Bethesda, MD 20892–4878, 301–594–2904, *ramanj@mail.nih.gov.*

*Name of Committee:* National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Clinical Trials SEP.

*Date:* June 11, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

*Contact Person:* Crina Frincu, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health 6701 Democracy Blvd., Suite 662, Bethesda, MD 20892, *cfrincu@mail.nih.gov*.

*Name of Committee:* National Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of Planning Grants for Dental, Oral and Craniofacial Tissue Regeneration Consortium Resource Center (R34) Applications.

*Date:* June 15, 2015.

*Time:* 8:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892.

*Contact Person:* Victor Henriquez, Ph.D., Scientific Review Officer, DEA/SRB/NIDCR, 6701 Democracy Blvd., Room 668, Bethesda, MD 20892–4878, 301–451–2405, *henriquv@nidcr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 11, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11707 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Omnibus SEP–14 Review Meeting.

*Date:* June 16, 2015.
*Time:* 8:30 a.m. to 5:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, MD 20850, (Telephone Conference Call).
*Contact Person:* Wlodek Lopaczynski, MD, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, MD 20850, 240–276–6458, *lopacw@mail.nih.gov.*

*Name of Committee:* National Cancer Institute, Special Emphasis Panel Utilizing the PLCO Biospecimens Resource (U01).
*Date:* June 23, 2015.
*Time:* 10:30 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 4W030, Rockville, MD 20850, (Telephone Conference Call).
*Contact Person:* Gerald G. Lovinger, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W266, Rockville, MD 20850, 240–276–6385, *lovingeg@mail.nih.gov.*
*Name of Committee:* National Cancer Institute, Special Emphasis Panel, SBIR Phase II, Bridge Awards (R44).
*Date:* July 7–8, 2015.
*Time:* 11:00 a.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2W032/2W034, Rockville, MD 20850, (Telephone Conference Call).
*Contact Person:* Kenneth L. Bielat, Ph.D., Scientific Review Officer, Research and Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, MD 20850, 240–276–6373, *bielatk@mail.nih.gov.*

*Name of Committee:* National Cancer Institute Special Emphasis Panel, NCI Omnibus, R03 & R21, SEP–7.
*Date:* July 9–10, 2015.
*Time:* 6:00 p.m. to 6:00 p.m.
*Agenda:* To review and evaluate grant applications.
*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.
*Contact Person:* Stanislav Vukmanovic, MD, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Rockville, MD 20850, 240–276–5188, *vukmanovics@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Melanie J. Gray-Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11705 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* President's Cancer Panel.
*Date:* July 9, 2015.
*Time:* 9:00 a.m. to 4:00 p.m.
*Agenda:* The Connected Cancer Patient: Vision for the Future.
*Place:* W Chicago—Lakeshore Hotel, 644 North Lake Shore Drive, Chicago, IL 60611.
*Contact Person:* Abby B. Sandler, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, Nci Center for Cancer Research, 9000 Rockville Pike, Building 31, Room B2B37, MSC 2590, Bethesda, MD 20892–8349 (301) 451–9399 *sandlera@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/pcp/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 11, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–11703 Filed 5–14–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2015–0268]**

### Certificate of Alternative Compliance for the P/V LUCIA, 1257462

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice.

**SUMMARY:** The Coast Guard announces that a Certificate of Alternative Compliance was issued for the passenger vessel LUCIA as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

**DATES:** The Certificate of Alternative Compliance was issued on April 3, 2015.

**ADDRESSES:** The docket for this notice is 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. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2015–0268 in the ''Keyword'' box, and then clicking ''Search.''

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call LT Steven Melvin, District Nine, Prevention Branch, U.S. Coast Guard, telephone 216–902–6343. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

#### Background and Purpose

As required by 33 U.S.C. 1605(c) and 33 CFR 81.18, the Coast Guard gives notice that it has issued a certificate of alternative compliance for the P/V LUCIA. The vessel's primary purpose is a passenger-touring vessel that operates on the Chicago River and near coastal waters of Lake Michigan in Southern Illinois. The unique design of the vessel did not lend itself to full compliance with Annex I of the Inland Rules Act, 33 U.S.C. 2071.

The Commandant, U.S. Coast Guard, certifies that full compliance with the Inland Rules Act would interfere with

the special functions and intent of the vessel and would not significantly enhance the safety of the vessel's operation. Placing the masthead light in the required position would interfere with vessel's ability to navigate on the Chicago River, which has several low bridges making the vessel vulnerable to damage.

The Certificate of Alternative Compliance authorizes the P/V LUCIA to deviate from the requirements set forth in Annex I of the Inland Rules Act by placing its masthead light on the pilothouse visor at a height of 13′7″ above the main deck.

This notice is issued under authority of 5 U.S.C. 552(a), 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: April 3, 2015.

**P. Albertson,**

*Captain, U.S. Coast Guard, Chief, Prevention Division, Ninth Coast Guard District.*

[FR Doc. 2015–11813 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–04–P**

---

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[1651–0013]**

### Agency Information Collection Activities: Entry and Manifest of Merchandise Free of Duty, Carrier's Certificate and Release

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; Extension of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Entry and Manifest of Merchandise Free of Duty, Carrier's Certificate and Release (CBP Form7523). 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 or to the information collected. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before June 15, 2015 to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this 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.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** (80 FR 12830) on March 11, 2015, 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. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub.L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Entry and Manifest of Merchandise Free of Duty, Carrier's Certificate of Release.

*OMB Number:* 1651–0013.

*Form Number:* CBP Form 7523.

*Abstract:* CBP Form 7523, *Entry and Manifest of Merchandise Free of Duty, Carrier's Certificate of Release,* is used by carriers and importers as a manifest for the entry of merchandise free of duty under certain conditions. CBP Form 7523 is also used by carriers to show that articles being imported are to be released to the importer or consignee, and as an inward foreign manifest for vehicles of less than 5 tons arriving from Canada or Mexico with merchandise conditionally free of duty. CBP uses this form to authorize the entry of such merchandise. CBP Form 7523 is authorized by 19 U.S.C. 1433, 1484 and 1498. It is provided for by 19 CFR 123.4 and 19 CFR 143.23. This form is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=7523&=Apply.*

*Current Actions:* CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 4,950.

*Estimated Number of Responses per Respondent:* 20.

*Estimated Total Annual Responses:* 99,000.

*Estimated Time per Response:* 5 minutes.

*Estimated Total Annual Burden Hours:* 8,247.

Dated: May 11, 2015.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2015–11720 Filed 5–14–15; 8:45 am]

**BILLING CODE 9111–14–P**

---

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[1651–0127]**

### Agency Information Collection Activities: Guarantee of Payment

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; extension of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Guarantee of Payment (CBP Form I–510). 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 or to the information collected. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before June 15, 2015 to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this 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.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** (80 FR 12831) on March 11, 2015, 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. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Guarantee of Payment.

*OMB Number:* 1651–00127.

*Form Number:* Form I–510.

*Abstract:* Section 253 of the Immigration and Nationality Act (INA) requires that an alien crewman found to be or suspected of being afflicted with any of the diseases named in section 255 of the INA shall be placed in a hospital for treatment and/or observation with the expense of such observation and/or treatment being borne by the carrier. The guarantee of payment for medical and other related expenses required by section 253 of the Act shall be executed by the owner, agent, consignee, commanding officer or master of the vessel or aircraft on CBP Form I–510, *Guarantee of Payment.* No vessel or aircraft can be granted clearance until such expenses are paid or their payment appropriately guaranteed. CBP Form I–510 collects information such as the name of the owner, agent, commander officer or master of the vessel or aircraft; the name of the crewman; the port of arrival; and signature of the guarantor. This form is provided for by 8 CFR 253.1 and is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=I-510*

*Action:* CBP proposes to extend the expiration date of this information collection with no change to the estimated burden hours or to CBP Form I–510.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 100.

*Estimated Total Annual Responses:* 100.

*Estimated Time per Response:* 5 minutes.

*Estimated Total Annual Burden Hours:* 8.

Dated: May 11, 2015.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2015–11812 Filed 5–14–15; 8:45 am]

BILLING CODE 9111–14–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4217–DR; Docket ID FEMA–2015–0002]**

### Kentucky; Major Disaster and Related Determinations

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

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Kentucky (FEMA–4217–DR), dated May 1, 2015, and related determinations.

**DATES:** *Effective date:* May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated May 1, 2015, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Kentucky resulting from severe storms, tornadoes, flooding, landslides, and mudslides during the period of April 2–17, 2015, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Kentucky.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Joe M. Girot, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Kentucky have been designated as adversely affected by this major disaster:

Bath, Bourbon, Carter, Elliott, Franklin, Jefferson, Lawrence, Madison, Rowan, and Scott Counties for Individual Assistance.

Bath, Bourbon, Breathitt, Bullitt, Clark, Elliott, Estill, Franklin, Jefferson, Johnson, Lawrence, Lee, Lewis, Madison, Magoffin, Metcalfe, Morgan,

Owsley, and Wolfe Counties for Public Assistance.

All areas within the Commonwealth of Kentucky are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–11837 Filed 5–14–15; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4211–DR; Docket ID FEMA–2015–0002]**

### Tennessee; Amendment No. 2 to Notice of a Major Disaster Declaration

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

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Tennessee (FEMA–4211–DR), dated April 2, 2015, and related determinations.

**DATES:** *Effective Date:* May 5, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Tennessee is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 2, 2015.

Claiborne, Cocke, Davidson, DeKalb, Greene, Hawkins, Pickett, Rhea, and Wayne Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–11818 Filed 5–14–15; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2015–0001]**

### Final Flood Hazard Determinations

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

**ACTION:** Final Notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The effective date of July 6, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

**ADDRESSES:** The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report

available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: April 23, 2015.

**Roy E. Wright,**

*Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

| Community | Community map repository address |
|---|---|
| **Hendry County, Florida, and Incorporated Areas Docket No.: FEMA–B–1353** | |
| City of Clewiston | Community Development Department, 121 Central Avenue, Clewiston, FL 33440. |
| City of La Belle | City Hall, 481 West Hickpochee Avenue, LaBelle, FL 33935. |
| Unincorporated Areas of Hendry County | Hendry County Building Department, 640 South Main Street, LaBelle, FL 33935. |
| **Waldo County, Maine (All Jurisdictions) Docket No.: FEMA–B–1415** | |
| City of Belfast | City Hall, 131 Church Street, Belfast, ME 04915. |
| Lime Island | Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333. |
| Little Bermuda Island | Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333. |
| Town of Belmont | Town Office, 613 Back Belmont Road, Belmont, ME 04952. |
| Town of Brooks | Town Hall, 15 Purple Heart Highway, Brooks, ME 04921. |
| Town of Burnham | Town Office, 247 South Horseback Road, Burnham, ME 04922. |
| Town of Frankfort | Town Office, 48A Main Road South, Frankfort, ME 04438. |
| Town of Freedom | Town Hall, 71 Pleasant Street, Freedom, ME 04941. |
| Town of Islesboro | Town Office, 150 Main Road, Islesboro, ME 04848. |
| Town of Knox | Town Office, 10 Abbott Road, Knox, ME 04986. |
| Town of Liberty | Town Hall, Seven Water Street, Liberty, ME 04949. |
| Town of Lincolnville | Town Office, 493 Hope Road, Lincolnville, ME 04849. |
| Town of Monroe | Town Hall, Eight Swan Lake Avenue, Monroe, ME 04951. |
| Town of Montville | Town Hall, 414 Center Road, Montville, ME 04941. |
| Town of Morrill | Town Hall, 44 Weymouth Road, Morrill, ME 04952. |
| Town of Northport | Town Office, 16 Beech Hill Road, Northport, ME 04849. |
| Town of Palermo | Town Hall, 45 North Palermo Road, Palermo, ME 04354. |
| Town of Prospect | Town Office, 958 Bangor Road, Prospect, ME 04981. |
| Town of Searsmont | Town Office, 37 Main Street South, Searsmont, ME 04973. |
| Town of Searsport | Town Office, One Union Street, Searsport, ME 04974. |
| Town of Stockton Springs | Town Office, 217 Main Street, Stockton Springs, ME 04981. |
| Town of Swanville | Town Hall, Six Townhouse Road, Swanville, ME 04915. |
| Town of Thorndike | Town Hall, 125 Mount View Road, Thorndike, ME 04986. |
| Town of Troy | Town Office, 129 Rogers Road, Troy, ME 04987. |
| Town of Unity | Town Office, 84 School Street, Unity, ME 04988. |
| Town of Waldo | Town Office, 629 Waldo Station Road, Waldo, ME 04915. |
| Town of Winterport | Town Office, 20 School Street, Winterport, ME 04496. |
| **Missoula County, Montana, and Incorporated Areas Docket No.: FEMA–B–1347** | |
| City of Missoula | 435 Ryman Street, Missoula, MT 59802. |
| Unincorporated Areas of Missoula County | 317 Woody Street, Missoula, MT 59802. |
| **Charles City County, Virginia (All Jurisdictions) Docket No.: FEMA–B–1412** | |
| Unincorporated Areas of Charles City County | Charles City County Department of Public Works, 10900 Courthouse Road, Charles City, VA 23030. |

[FR Doc. 2015–11844 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2015–0001]**

### Changes in Flood Hazard Determinations

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

**ACTION:** Final notice.

**SUMMARY:** New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

**DATES:** The effective date for each LOMR is indicated in the table below.

**ADDRESSES:** Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: April 23, 2015.

**Roy E. Wright,**

*Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Effective date of modification | Community No. |
|---|---|---|---|---|---|
| Arkansas: Benton (FEMA Docket No.: B–1458). | City of Rogers (14–06–1977P). | The Honorable Greg Hines, Mayor, City of Rogers, 301 West Chestnut Street, Rogers, AR 72756. | City Hall, 301 West Chestnut Street, Rogers, AR 72756. | February 20, 2015 ..... | 050013 |
| District of Columbia: Washington (FEMA Docket No.: B–1458). | District of Columbia (14–03–2215P). | The Honorable Muriel Bowser, Mayor, District of Columbia, 1350 Pennsylvania Avenue, Northwest, Suite 316, Washington, DC 20004. | Department of the Environment, 1200 1st Street, Northeast, 5th Floor, Washington, DC 20002. | March 4, 2015 ..... | 110001 |
| Maryland: Montgomery (FEMA Docket No.: B–1458). | Unincorporated areas of Montgomery County (13–03–1642P). | The Honorable Isiah Leggett, Montgomery County Executive, 101 Monroe Street, 2nd Floor, Rockville, MD 20850. | Montgomery County Department of Permitting Services, 255 Rockville Pike, 2nd Floor, Rockville, MD 20850. | March 2, 2015 ..... | 240049 |
| Massachusetts: | | | | | |
| Middlesex (FEMA Docket No.: B–1458). | City of Lowell (14–01–1641P). | Mr. Kevin J. Murphy, Manager, City of Lowell, 375 Merrimack Street, 2nd Floor, Room 43, Lowell, MA 01852. | City Hall, 375 Merrimack Street, Lowell, MA 01852. | February 20, 2015 ..... | 250201 |
| Middlesex (FEMA Docket No.: B–1458). | Town of Chelmsford (14–01–1641P). | The Honorable Patricia Wojtas, Chairman, Chelmsford Town Board of Selectmen, 50 Billerica Road, 2nd Floor, Chelmsford, MA 01824. | Town Hall, 50 Billerica Road, Chelmsford, MA 01824. | February 20, 2015 ..... | 250188 |
| New York: | | | | | |
| Dutchess (14–02–0532P) (FEMA Docket No.: B–1444). | Town of Beekman (14–02–0532P). | The Honorable Barbara Zulauf, Supervisor, Town of Beekman, 4 Main Street, Poughquag, NY 12570. | Beekman Town Hall, 4 Main Street, Poughquag, NY 12570. | March 2, 2015 ..... | 361333 |
| Rockland (FEMA Docket No.: B–1444). | Town of Clarkstown (14–02–1889P). | The Honorable Alexander J. Gromack, Supervisor, Town of Clarkstown, 10 Maple Avenue, New City, NY 10956. | Clarkstown Town Hall, 10 Maple Avenue, New City, NY 10956. | February 18, 2015 ..... | 360679 |
| Texas: | | | | | |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Effective date of modification | Community No. |
|---|---|---|---|---|---|
| Bexar (FEMA Docket No.: B–1458). | City of San Antonio (13–06–2738P). | The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283. | Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204. | March 2, 2015 ..... | 480045 |
| Bexar (FEMA Docket No.: B–1458). | City of San Antonio (14–06–0171P). | The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283. | Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204. | March 2, 2015 ..... | 480045 |
| Bexar (FEMA Docket No.: B–1458). | Unincorporated areas of Bexar County (14–06–0171P). | The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207. | March 2, 2015 ..... | 480035 |
| Bexar (FEMA Docket No.: B–1458). | Unincorporated areas of Bexar County (14–06–3173P). | The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207. | March 4, 2015 ..... | 480035 |
| Collin (FEMA Docket No.: B–1467). | City of Plano (14–06–0359P). | The Honorable Harry LaRosiliere, Mayor, City of Plano, 1520 K Avenue, Plano, TX 75074. | Department of Engineering, 1520 K Avenue, Plano, TX 75074. | March 20, 2015 ..... | 480140 |
| Comal (FEMA Docket No.: B–1458). | City of New Braunfels (13–06–4372P).. | The Honorable Barron Casteel, Mayor, City of New Braunfels, 424 South Castell Avenue, New Braunfels, TX 78130. | Municipal Building, 424 South Castell Avenue, New Braunfels, TX 78130. | February 26, 2015 ..... | 485493 |
| Dallas (FEMA Docket No.: B–1458). | City of Rowlett (14–06–2443P). | The Honorable Todd W. Gottel, Mayor, City of Rowlett, 4000 Main Street, Rowlett, TX 75088. | Development Services Building, 3901 Main Street, Rowlett, TX 75088. | March 13, 2015 ..... | 480185 |
| Dallas and Denton (FEMA Docket No.: B–1467). | City of Coppell (14–06–2759P). | The Honorable Karen Hunt, Mayor, City of Coppell, P.O. Box 9478, Coppell, TX 75019. | Engineering Department, 265 Parkway Boulevard, Coppell, TX 75019. | March 19, 2015 ..... | 480170 |
| Ellis (FEMA Docket No.: B–1467). | City of Midlothian (14–06–1375P). | The Honorable Bill Houston, Mayor, City of Midlothian, 104 West Avenue E, Midlothian, TX 76065. | City Hall, 104 West Avenue E, Midlothian, TX 76065. | March 5, 2015 ..... | 480801 |
| El Paso (FEMA Docket No.: B–1458). | Unincorporated areas of El Paso County, (13–06–3651P). | The Honorable Veronica Escobar, El Paso County Judge, 500 East San Antonio Street, Suite 301, El Paso, TX 79901. | El Paso County Public Works Department, 800 East Overland Avenue, Suite 407, El Paso, TX 79901. | March 4, 2015 ..... | 480212 |
| Garland (FEMA Docket No.: B–1467). | City of Gonzales (14–06–1672P). | The Honorable Robert A. Logan, Mayor, City of Gonzales, 820 St. Joseph Street, Gonzales, TX 78629. | 820 St. Joseph Street, Gonzales, TX 78629. | March 25, 2015 ..... | 480254 |
| Kendall (FEMA Docket No.: B–1458). | Unincorporated areas of Kendall County (14–06–1363P). | The Honorable Darrel L. Lux, Kendall County Judge, 201 East San Antonio Avenue, Suite 122, Boerne, TX 78006. | Kendall County Development and Floodplain Management Office, 201 East San Antonio Avenue, Suite 101, Boerne, TX 78006. | February 17, 2015 ..... | 480417 |
| Tarrant (FEMA Docket No.: B–1467). | City of Bedford (14–06–2009P). | The Honorable Jim Griffin, Mayor, City of Bedford, 2000 Forest Ridge Drive, Bedford, TX 76021. | Public Works Department, 1813 Reliance Parkway, Bedford, TX 76021. | March 19, 2015 ..... | 480585 |
| Tarrant (FEMA Docket No.: B–1467). | City of Fort Worth (14–06–2425P). | The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX76102. | City Hall, 1000 Throckmorton Street, Fort Worth, TX 76102. | March 6, 2015 ..... | 480596 |
| Williamson (FEMA Docket No.: B–1458). | City of Georgetown (13–06–1572P). | The Honorable Dale Ross, Mayor, City of Georgetown, 113 East 8th Street, Georgetown, TX 78626. | City Hall, 113 East 8th Street, Georgetown, TX 78626. | February 26, 2015 ..... | 480668 |
| Williamson (FEMA Docket No.: B–1458). | City of Round Rock (14–06–2866P). | The Honorable Alan McGraw, Mayor, City of Round Rock, 221 East Main Street, Round Rock, TX 78664. | Department of Utilities and Environmental Services, 2008 Enterprise Drive, Round Rock, TX 78664. | March 13, 2015 ..... | 481048 |

[FR Doc. 2015–11840 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2015–0001]**

### Final Flood Hazard Determinations

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

**ACTION:** Final notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The effective date of June 16, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

**ADDRESSES:** The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: April 22, 2015.

**Roy E. Wright,**

*Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

I. Watershed-based studies:

| Community | Community map repository address |
|---|---|
| **Upper Grand Watershed** | |
| **Ringgold County, Iowa, and Incorporated Areas Docket No.: FEMA–B–1356** | |
| City of Benton | Ringgold County Courthouse, 109 West Madison Street, Mount Ayr, IA 50854. |
| City of Diagonal | City Hall, 601 West Eight Street, Diagonal, IA 50854. |
| City of Maloy | City Hall, 204 Carter Street, Maloy, IA 50836. |
| City of Mount Ayr | City Hall, 200 South Taylor Street, Mount Ayr, IA 50854. |
| City of Shannon City | City Hall, 302 Union Street, Shannon City, IA 50861. |
| Unincorporated Areas of Ringgold County | Ringgold County Courthouse, 109 West Madison Street, Mount Ayr, IA 50854. |
| **West Nishnabotna Watershed** | |
| **Shelby County, Iowa, and Incorporated Areas Docket No.: FEMA–B–1410** | |
| City of Defiance | City Hall, 206 Main Avenue, Defiance, IA 51527. |
| City of Earling | City Clerk Office, 117 Main Street, Earling, IA 51530. |
| City of Harlan | City Hall, 711 Durant Street, Harlan, IA 51537. |
| City of Irwin | City Hall, 504 Ann Street, Irwin, IA 51446. |
| City of Kirkman | Community Hall, 106 State Street, Kirkman, IA 51447. |
| City of Panama | City Hall, 111 Main Street, Panama, IA 51562. |
| City of Portsmouth | City Hall, 2nd Avenue and Main Street, Portsmouth, IA 51565. |
| Unincorporated Areas of Shelby County | Shelby County Engineer Office, 1411 Industrial Parkway, Harlan, IA 51537. |
| **Upper Grand Watershed** | |
| **Caldwell County, Missouri, and Incorporated Areas Docket No.: FEMA–B–1404** | |
| City of Braymer | City Hall, 108 East 2nd Street, Braymer, MO 64624. |
| City of Kingston | City Hall, 30 West Main Street, Kingston, MO 64650. |
| Unincorporated Areas of Caldwell County | County Courthouse, 49 East Main Street, Kingston, MO 64650. |
| **Gentry County, Missouri, and Incorporated Areas Docket No.: FEMA–B–1404** | |
| City of Albany | City Hall, 106 East Clay Street, Albany, MO 64402. |

| Community | Community map repository address |
|---|---|
| City of Stanberry | City Hall, 130 West 1st Street, Stanberry, MO 64489. |
| Unincorporated Areas of Gentry County | County Courthouse, 200 West Clay Street, Albany, MO 64402. |
| Village of Darlington | Gentry County Courthouse, 200 West Clay Street, Albany, MO 64402. |
| Village of Gentry | Gentry County Courthouse, 200 West Clay Street, Albany, MO 64402. |

II. Non-watershed-based studies:

| Community | Community map repository address |
|---|---|
| **Buchanan County, Iowa, and Incorporated Areas Docket No.: FEMA–B–1404** | |
| City of Independence | City Hall, 331 1st Street East, Independence, IA 50644. |
| Unincorporated Areas of Buchanan County | Buchanan County Zoning Office, 210 5th Avenue Northeast, Suite I, Independence, IA 50644. |
| **Van Buren, Iowa, and Incorporated Areas Docket No.: FEMA–B–1410** | |
| City of Keosauqua | City Hall, 804 1st Street, Keosauqua, IA 52565. |
| Van Buren County | Van Buren County Courthouse, 406 Dodge Street, Keosauqua, IA 52565. |

[FR Doc. 2015–11816 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4217–DR; Docket ID FEMA–2015–0002]**

### Kentucky; Amendment No. 1 to Notice of a Major Disaster Declaration

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

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA–4217–DR), dated May 1, 2015, and related determinations.

**DATES:** *Effective Date:* May 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the Commonwealth of Kentucky is hereby amended to make available all Individual Assistance programs for the following areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 1, 2015.

Bath, Bourbon, Carter, Elliott, Franklin, Jefferson, Lawrence, Madison, Rowan, and Scott Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–11833 Filed 5–14–15; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–B–1505]**

### Changes in Flood Hazard Determinations

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

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard

determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: April 22, 2015.

**Roy E. Wright,**

*Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---|---|---|---|---|---|---|
| Alabama: Shelby | Unincorporated areas of Shelby County (14–04–A927P). | The Honorable Rick Shepherd, Chairman, Shelby County Board of Commissioners, 200 West College Street, Columbiana, AL 35051. | Shelby County Engineer's Office, 506 Highway 70, Columbiana, AL 35051. | *http://www.msc.fema.gov/lomc* | June 1, 2015 | 010191 |
| Arizona: | | | | | | |
| Maricopa | City of Phoenix (14-09-3346P). | The Honorable Greg Stanton, Mayor, City of Phoenix, 200 West Washington Street, 11th Floor, Phoenix, AZ 85003. | Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003. | *http://www.msc.fema.gov/lomc* | May 28, 2015 | 040051 |
| Mojave | City of Bullhead City (14–09–3576P). | The Honorable Tom Brady, Mayor, City of Bullhead City, 2355 Trane Road, Bullhead City, AZ 86442. | Emergency Management Department, 1255 Marina Boulevard, Bullhead City, AZ 86442. | *http://www.msc.fema.gov/lomc* | May 14, 2015 | 040125 |
| Yavapai | Town of Clarkdale (14–09–3026P). | The Honorable Doug Von Gausig, Mayor, Town of Clarkdale, P.O. Box 308, Clarkdale, AZ 86324. | Public Works Department, 890 Main Street, Clarkdale, AZ 86324. | *http://www.msc.fema.gov/lomc* | May 14, 2015 | 040095 |
| Yavapai | Unincorporated areas of Yavapai County (14–09–3026P). | The Honorable Rowle P. Simmons, Chairman, Yavapai County Board of Supervisors, 1015 Fair Street, Prescott, AZ 86305. | Yavapai County Flood Control District, 500 South Marina Street, Prescott, AZ 86303. | *http://www.msc.fema.gov/lomc* | May 14, 2015 | 040093 |
| California: | | | | | | |
| Riverside | Unincorporated areas of Riverside County (14–09–2663P). | The Honorable Marion Ashley, Chairman, Riverside County Board of Supervisors, 4080 Lemon Street, 5th Floor, Riverside, CA 92501. | Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501. | *http://www.msc.fema.gov/lomc* | May 28, 2015 | 060245 |
| Sacramento | City of Folsom (15–09–0527P). | The Honorable Andy Morin, Mayor, City of Folsom, 50 Natoma Street, Folsom, CA 95630. | Public Works Department, 50 Natoma Street, Folsom, CA 95630. | *http://www.msc.fema.gov/lomc* | May 28, 2015 | 060263 |
| Colorado: | | | | | | |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---|---|---|---|---|---|---|
| Arapahoe | City of Aurora (14–08–1180P). | The Honorable Steve Hogan, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012. | City Hall, 15151 East Alameda Parkway, Aurora, CO 80012. | *http://www.msc.fema.gov/lomc* | May 22, 2015 | 080002 |
| Arapahoe | City of Centennial (14–08–1180P). | The Honorable Cathy Noon, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112. | Southeast Metro Stormwater Authority, 7437 South Fairplay Street, Centennial, CO 80112. | *http://www.msc.fema.gov/lomc* | May 22, 2015 | 080315 |
| Arapahoe | Unincorporated areas of Arapahoe County (14–08–1180P). | The Honorable Nancy Doty, Chair, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120. | Arapahoe County Public Works Department, 6924 South Lima Street, Centennial, CO 80112. | *http://www.msc.fema.gov/lomc* | May 22, 2015 | 080011 |
| Ouray | Town of Ridgway (14–08–1315P). | The Honorable John Clark, Mayor, Town of Ridgway, P.O. Box 10, Ridgway, CO 81432. | Town Hall, 201 North Railroad Street, Ridgway, CO 81432. | *http://www.msc.fema.gov/lomc* | May 29, 2015 | 080138 |
| Florida: | | | | | | |
| Bradford | City of Starke (15–04–2615P). | The Honorable Travis Woods, Mayor, City of Starke, P.O. Drawer C, Starke, FL 32091. | City Clerk's Office, 209 North Thompson Street, Starke, FL 32091. | *http://www.msc.fema.gov/lomc* | May 15, 2015 | 120017 |
| Collier | City of Marco Island (15–04–0522P). | The Honorable Larry Sacher, Chairman, City of Marco Island Council, 50 Bald Eagle Drive, Marco Island, FL 34145. | City Hall, 50 Bald Eagle Drive, Marco Island, FL 34145. | *http://www.msc.fema.gov/lomc* | May 7, 2015 | 120426 |
| Lee | Unincorporated areas of Lee County (14–04–8329P). | The Honorable Brian Hamman, Chairman, Lee County Board of Commissioners, P.O. Box 398, Fort Myers, FL 33902. | Lee County Community Development Department, 1500 Monroe Street, 2nd Floor, Fort Meyers, FL 33901. | *http://www.msc.fema.gov/lomc* | May 12, 2015 | 125124 |
| Manatee | Unincorporated areas of Manatee County (14–04–8724P). | The Honorable Larry Bustle, Chairman, Manatee County Board of Commissioners, 1112 Manatee Avenue West, 9th Floor, Bradenton, FL 34205. | Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205. | *http://www.msc.fema.gov/lomc* | June 5, 2015 | 120153 |
| Monroe | Village of Islamorada (14–04–A708P). | The Honorable Mike Forester, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036. | Village Hall, 87000 Overseas Highway, Islamorada, FL 33036. | *http://www.msc.fema.gov/lomc* | May 4, 2015 | 120424 |
| Monroe | Unincorporated areas of Monroe County (14–04–A180P). | The Honorable Danny Kolhage, Mayor, Monroe County Board of Commissioners, 1100 Simonton Street, Key West, FL 33040. | Monroe County Planning and Environmental Resources Department, 2798 Overseas Highway, Marathon, FL 33050. | *http://www.msc.fema.gov/lomc* | May 7, 2015 | 125129 |
| Seminole | City of Longwood (14–04–7277P). | The Honorable John C. Maingot, Mayor, City of Longwood, 175 West Warren Avenue, Longwood, FL 32750. | Building and Planning Department, 174 West Church Avenue, Longwood, FL 32750. | *http://www.msc.fema.gov/lomc* | May 15, 2015 | 120292 |
| Seminole | Unincorporated areas of Seminole County (14–04–7277P). | The Honorable Bob Dallari, Chairman, Seminole County Board of Commissioners, 1101 East 1st Street, Sanford, FL 32771. | Seminole County Building Division, 1101 East 1st Street, Sanford, FL 32771. | *http://www.msc.fema.gov/lomc* | May 15, 2015 | 120289 |
| St. Johns | Unincorporated areas of St. Johns County (14–04–8520P). | The Honorable Rachael Bennett, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084. | St. Johns County Administrative Building, 4020 Lewis Speedway, St. Augustine, FL 32084. | *http://www.msc.fema.gov/lomc* | May 14, 2015 | 125147 |
| Georgia: | | | | | | |
| Cherokee | Unincorporated areas of Cherokee County (14–04–8555P). | The Honorable L.B. Ahrens, Chairman, Cherokee County Board of Commissioners, 1130 Bluffs Parkway, Canton, GA 30114. | Cherokee County Administrative Office, 130 East Main Street, Suite 106, Canton, GA 30114. | *http://www.msc.fema.gov/lomc* | May 18, 2015 | 130424 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---|---|---|---|---|---|---|
| Cobb | City of Smyrna (14–04–9804P). | The Honorable Arthur Max Bacon, Mayor, City of Smyrna, 2800 King Street, Smyrna, GA 30080. | City Engineer's Office, 2800 King Street, Smyrna, GA 30080. | *http://www.msc.fema.gov/lomc* | May 18, 2015 | 130057 |
| Columbia | Unincorporated areas of Columbia County (15–04–1887P). | The Honorable Ron C. Cross, Chairman, Columbia County Board of Commissioners, P.O. Box 498, Evans, GA 30809. | Columbia County Planning Department, 603 Ronald Reagan Drive, Building B, 1st Floor, Evans, GA 30809. | *http://www.msc.fema.gov/lomc* | May 28, 2015 | 130059 |
| Kentucky: | | | | | | |
| Scott | City of Georgetown (14–04–4874P). | The Honorable Everett Varney, Mayor, City of Georgetown, 100 Court Street, Georgetown, KY 40324. | Planning Commission, 230 East Main Street, Georgetown, KY 40324. | *http://www.msc.fema.gov/lomc* | May 29, 2015 | 210208 |
| Scott | Unincorporated areas of Scott County (14–04–4874P). | The Honorable George Lusby, Scott County Judge, 101 East Main Street, Georgetown, KY 40324. | Scott County Building Inspections Department, 100 Court Street, Georgetown, KY 40324. | *http://www.msc.fema.gov/lomc* | May 29, 2015 | 210207 |
| Mississippi: Rankin | City of Brandon (14–04–8704P). | The Honorable Butch Lee, Mayor, City of Brandon, P.O. Box 1539, Brandon, MS 39043. | City Hall, 1000 Municipal Drive, Brandon, MS 39042. | *http://www.msc.fema.gov/lomc* | May 12, 2015 | 280143 |
| Montana: Ravalli | Unincorporated areas of Ravalli County (15–08–0109P). | The Honorable Jeff Burrows, Chairman, Ravalli County Board of Commissioners, 215 South 4th Street, Suite A, Hamilton, MT 59840. | Floodplain Map Repository, 215 South 4th Street, Suite A, Hamilton, MT 59840. | *http://www.msc.fema.gov/lomc* | June 8, 2015 | 300061 |
| Nevada: Douglas | Unincorporated areas of Douglas County (14–09–4114P). | The Honorable Doug N. Johnson, Chairman, Douglas County Board of Commissioners, P.O. Box 218, Minden, NV 89423. | Douglas County Public Works Department, 1615 8th Street, Minden, NV 89423. | *http://www.msc.fema.gov/lomc* | May 28, 2015 | 320008 |
| North Carolina: | | | | | | |
| Cabarrus | Town of Harrisburg (14–04–6011P). | The Honorable Steve Sciascia, Mayor, Town of Harrisburg, 4100 Mail Street, Harrisburg, NC 28075. | Planning Department, 4100 Main Street, Harrisburg, NC 28075. | *http://www.msc.fema.gov/lomc* | February 26, 2015. | 370038 |
| Durham | City of Durham (14–04–4200P). | The Honorable William V. Bell, Mayor, City of Durham, 101 City Hall Plaza, Durham, NC 27701. | Public Works Department, 101 City Hall Plaza, Durham, NC 27701. | *http://www.msc.fema.gov/lomc* | February 17, 2015. | 370086 |
| South Carolina: | | | | | | |
| Beaufort | Town of Bluffton (15–04–2707P). | The Honorable Lisa Sulka, Mayor, Town of Bluffton, 20 Bridge Street, Bluffton, SC 29910. | Growth Management Customer Service Center, 20 Bridge Street, Bluffton, SC 29910. | *http://www.msc.fema.gov/lomc* | June 5, 2015 | 450251 |
| Charleston | Town of Mount Pleasant (15–04–0360P). | The Honorable Linda Page, Mayor, Town of Mount Pleasant, 100 Ann Edwards Lane, Mount Pleasant, SC 29464. | Town Hall, 100 Ann Edwards Lane, Mount Pleasant, SC 29464. | *http://www.msc.fema.gov/lomc* | June 1, 2015 | 455417 |
| Richland | Unincorporated areas of Richland County (14–04–5349P). | The Honorable Norman Jackson, Chairman, Richland County Council, P.O. Box 192, Columbia, SC 29201. | Richland County Floodplain Coordinator, 2020 Hampton Street, 1st Floor, Columbia, SC 29204. | *http://www.msc.fema.gov/lomc* | May 18, 2015 | 450170 |
| South Dakota: | | | | | | |
| Lincoln | Town of Harrisburg (14–08–0638P). | The Honorable Julie Burke-Bowen, Mayor, Town of Harrisburg, P.O. Box 26, Harrisburg, SD 57032. | City Hall, 203 Prairie Street, Harrisburg, SD 57032. | *http://www.msc.fema.gov/lomc* | May 22, 2015 | 460114 |
| Lincoln | Unincorporated areas of Lincoln County (14–08–0638P). | The Honorable Dale Long, Chairman, Lincoln County Board of Commissioners, 104 North Main Street, Canton, SD 57013. | Lincoln County Court House, 105 East 5th Street, Canton, SD 57013. | *http://www.msc.fema.gov/lomc* | May 22, 2015 | 460277 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---|---|---|---|---|---|---|
| Tennessee: Shelby | Town of Collierville (14–04–6821P). | The Honorable Stan Joyner, Jr., Mayor, Town of Collierville, 500 Poplar View Parkway, Collierville, TN 38017. | Town Hall, 500 Poplar View Parkway, Collierville, TN 38017. | *http://www.msc.fema.gov/lomc* | May 8, 2015 ..... | 470263 |
| Utah: | | | | | | |
| Washington .... | City of St. George (14–08–1160P). | The Honorable Jon Pike, Mayor, City of St. George, 175 East 200 North, St. George, UT 84770. | Engineering Department, 175 East 200 North, St. George, UT 84770. | *http://www.msc.fema.gov/lomc* | May 14, 2015 ..... | 490177 |
| Washington .... | Unincorporated areas of Washington County (14–08–1160P). | The Honorable James J. Eardley, Chairman, Washington County Board of Commissioners, 197 East Tabernacle Street, St. George, UT 84770. | Washington County Planning Department, 197 East Tabernacle Street, St. George, UT 84770. | *http://www.msc.fema.gov/lomc* | May 14, 2015 ..... | 490224 |

[FR Doc. 2015–11848 Filed 5–14–15; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID: FEMA–2015–0008; OMB No. 1660–0030]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request; Manufactured Housing Operations Forms

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

**ACTION:** Notice.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

**DATES:** Comments must be submitted on or before June 15, 2015.

**ADDRESSES:** 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 Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, facsimile number (202) 212–4701, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### Collection of Information

*Title:* Manufactured Housing Operations Forms.

*Type of information collection:* Revision of a currently approved information collection.

*OMB Number:* 1660–0030.

*Form Titles and Numbers:* FEMA Form 010–0–09, Request for the Site Inspection; FEMA Form 010–0–10, Landowner's Authorization Ingress-Egress Agreement; FEMA Form 009–0–138, Manufactured Housing Unit Inspection Report; FEMA Form 009–0–136, Unit Installation Work Order; FEMA Form 009–0–130, Maintenance Work Order.

*Abstract:* As authorized under The Robert T. Stafford Disaster Relief and Emergency Assistance Act, FEMA provides temporary housing units to eligible survivors of federally declared disasters. 42 U.S.C. 5174. This information is required to determine whether the infrastructure of the site supports the installation of a temporary housing unit. This collection also obtains permission to place the unit on the property. The property owner certifies that they will not have a lien placed against the unit for their own debts, thus ensuring they will maintain the property so that FEMA can remove the unit when required.

*Affected Public:* Individuals or households; business or other for-profit.

*Estimated Number of Respondents:* 25,000.

*Estimated Total Annual Burden Hours:* 4,250 hours.

*Estimated Cost:* The estimated annual cost to respondents for the hour burden is $134,657.00. There are no annual costs to respondents' operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $2,076,300.

Dated: May 8, 2015.

**Janice Waller,**

*Acting Director, Records Management Division, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.*

[FR Doc. 2015–11850 Filed 5–14–15; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID: FEMA–2015–0004; OMB No. 1660—NEW]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request; Direct Housing Program Forms

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

**ACTION:** Notice.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and

the actual data collection instruments FEMA will use.

**DATES:** Comments must be submitted on or before June 15, 2015.

**ADDRESSES:** 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 Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, facsimile number (202) 212–4701, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## Collection of Information

*Title:* Direct Housing Program Forms.

*Type of information collection:* New information collection.

*OMB Number:* 1660–NW90.

*Form Titles and Numbers:* FEMA Form 009–0–137, Unit Pad Requirements—Information Checklist; FEMA Form 009–0–131, Sales Calculation Worksheet; FEMA Form 009–0–129, Ready for Occupancy; FEMA Form 009–0–134, Recertification Worksheet; FEMA Form 009–0–135, Temporary Housing Agreement.

*Abstract:* The Robert T. Stafford Disaster Relief and Emergency Assistance Act authorizes the President to provide temporary housing units to eligible applicants who require temporary housing as a result of a major disaster. 42 U.S.C. 5174. The information collected provides the information necessary to determine the feasibility of the site for placement of temporary housing and so that FEMA can have access to place temporary housing units as well as retrieve it at the end of the use.

*Affected Public:* Individuals or households; business or other for-profit.

*Estimated Number of Respondents:* 25,000.

*Estimated Total Annual Burden Hours:* 4,165 hours.

*Estimated Cost:* The estimated annual cost to respondents for the hour burden is $157,753.54. There are no annual costs to respondents' operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $2,864,760.00.

Dated: May 8, 2015.

**Janice Waller,**

*Acting Director, Records Management Division, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.*

[FR Doc. 2015–11849 Filed 5–14–15; 8:45 am]

BILLING CODE 9111–23–P

---

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5872–N–01]**

## Notice of Extension of Time for Completion of Manufacturer Notification and Correction Plan

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

**ACTION:** Notice of extension of time.

**SUMMARY:** This notice advises the public that HUD received a request from Cavco Industries (Cavco) for an extension of time to fully implement its plan to notify purchasers and correct certain manufactured homes built and sold by Cavco that were installed with Kidde combined smoke and carbon monoxide alarms imported by Walter Kidde Portable Equipment Inc., that were subsequently recalled by the Consumer Product Safety Commission. After reviewing Cavco's request, HUD determined that Cavco has shown good cause and granted its request for an extension. The requested extension is granted until August 24, 2015.

**FOR FURTHER INFORMATION CONTACT:** Pamela Beck Danner, Administrator and Designated Federal Official (DFO), Office of Manufactured Housing Programs, Office of Housing Department of Housing and Urban Development, 451 Seventh Street SW., Room 9166, Washington, DC 20410, telephone 202–708–6423 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339.

**DATES:** *Effective Date:* April 24, 2015.

**SUPPLEMENTARY INFORMATION:** The National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401–5426) (the Act) authorizes HUD to establish the Federal Manufactured Home Construction and Safety Standards (Construction and Safety Standards), codified in 24 CFR part 3280. Section 615 of the Act (42 U.S.C. 5414) requires that manufacturers of manufactured homes notify purchasers if the manufacturer determines, in good faith, that a defect exists or is likely to exist in more than one home manufactured by the manufacturer and the defect relates to the Construction and Safety Standards or constitutes an imminent safety hazard to the purchaser of the manufactured home. The notification shall also inform purchasers whether the defect is one that the manufacturer will have corrected at no cost or is one that must be corrected at the expense of the purchaser/owner. The manufacturer is responsible to notify purchasers of the defect within a reasonable time after discovering the defect.

HUD's procedural and enforcement provisions at 24 CFR part 3282, subpart I (Subpart I) implement these notification and correction requirements. If a manufacturer determines that it is responsible for providing notification under 3282.405 and correction under 3282.406, the manufacturer must prepare a plan for notifying purchasers of the homes containing the defect pursuant to 3282.408 and 3282.409. Notification of purchasers must be accomplished by certified mail or other more expeditious means that provides a receipt. Notification must be provided to each retailer or distributor to whom any manufactured home in the class of homes containing the defect was delivered, to the first purchaser of each manufactured home in the class of manufactured homes containing the defect, and to other persons who are a registered owners of a manufactured home in the class of homes containing the defect. The manufacturer must complete the implementation of the plan for notification and correction on or before the deadline approved by the State Administrative Agency or HUD. Under 3282.410(c), the manufacturer may request an extension of the deadline if it shows good cause for the extension and the Secretary of HUD decides that the extension is justified and not contrary to the public interest. If the request for extension is approved, 3282.410(c) requires that HUD publish notice of the extension in the **Federal Register**.

On November 14, 2014, Cavco [1] notified HUD that it received information that a defective product was systematically installed into homes during the manufacturing process. Specifically, the homes were installed with certain Kidde combined smoke and carbon monoxide alarms which were subsequently voluntarily recalled by Kidde in conjunction with the Consumer Product Safety Commission.

[1] Information about Cavco Industries can be found at *http://www.cavco.com.*

To view the recall notice, please visit *http://www.cpsc.gov/en/Recalls/2014/Kidde-Recalls-Smoke-and-Combination-SmokeCO-Alarms/.* On December 16, 2014, Cavco submitted a revised plan of notification and correction. Pursuant to its notification and correction plan, Cavco has attempted to notify all affected homeowners by certified mail and telephone and send free-of-charge replacement Kidde combined smoke and carbon monoxide alarms to affected homeowners or install such replacement when requested by the homeowner. HUD approved the Cavco plan of notification and correction on December 29, 2014.

Since receipts for all certified letters were not returned and in some cases a valid phone number was not available, Cavco, by letter dated April 24, 2015, requested an extension of 120 days to complete the notification and correction process. This notice advises that HUD finds that Cavco has shown good cause and that the extension is justified and not contrary to the public interest and, on April 24, 2015, granted the requested extension until August 24, 2015, to permit Cavco to continue its good faith efforts to contact the affected homeowners who did not receive a certified letter, and to replace Kidde combined smoke and carbon monoxide alarms at no cost to affected homeowners.

Dated: May 12, 2015.

**Pamela Beck Danner,**

*Administrator, Office of Manufactured Housing Programs.*

[FR Doc. 2015–11805 Filed 5–14–15; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5830–N–02]**

## Notice of Emergency Information Collection and Request for Comment: Assessment of Technology Needs in HUD-Subsidized Housing

**AGENCY:** Office of the General Counsel, HUD.

**ACTION:** Notice.

**SUMMARY:** Through this notice, and in accordance with the Paperwork Reduction Act of 1995, HUD invites comment on a proposed information collection for the purpose of helping HUD assess technology needs, such as access to high-speed Internet, in HUD-subsidized housing. HUD is requesting emergency processing of this request because philanthropic foundations, nonprofit organizations, private sector entities, and others have expressed interest in helping residents housed with HUD assistance to narrow their technology infrastructure and digital literacy gaps. The questions included in the information collection will enable HUD to assess the technology needs of residents housed with HUD assistance, the commitment of communities and Public Housing Agencies (PHAs) to narrowing these technology gaps, and the capacity of such jurisdictions to successfully utilize the type of assistance that is being offered. The earlier that HUD can obtain this information, the earlier that HUD may be able to benefit from the generosity of the various organizations that have offered assistance.

**DATES:** *Comment Due Date:* May 22, 2015.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

### A. Overview of Information Collection

*Title of Information Collection:* Assessment of Technology Needs in HUD-Subsidized Housing.

*OMB Approval Number:* Pending.

*Type of Request:* New.

*Form Number:* Pending.

*Description of the need for the information and proposed use:* This assessment will provide the data necessary to inform subsequent conversations with communities and Public Housing Agencies (PHAs) on the technology needs of residents housed with HUD assistance. The data will also inform the design and implementation of assistance efforts to narrow the technology infrastructure and digital literacy gaps in such housing, such as the absence of access to high-speed Internet. The standardized questions cover broad areas of relevance to assessing the technology needs of communities and PHAs, including: (1) Demographics of the populations served (including such factors as age, income, and education); (2) physical and technological infrastructure in the subsidized housing or that could be made available by the jurisdiction; and (3) potential use of federal and local resources to address the technology needs if these resources were made available. In addition, the assessment provides for communities and PHAs to provide any information pertaining to these topic areas that they may wish to note and that is not covered by the standardized questions, which would help better identify their technology needs.

*Respondents (i.e. affected public):* Communities (*i.e.,* city, tribal nation, or other target area) and PHAs.

*Estimated Number of Respondents:* 3400.

*Estimated Number of Responses:* 50.

*Frequency of Response:* Once.

*Average Hours per Response:* Three hours.

*Total Estimated Burdens:* 450 hours.

| Information collection | Number of respondents | Frequency of response | Responses per annum | Burden hour per response | Annual burden hours | Hourly cost per response | Annual cost |
|---|---|---|---|---|---|---|---|
| Demographics | 3,400 | once | 50 | 1 | 1 | 0 | 0 |

| Information collection | Number of respondents | Frequency of response | Responses per annum | Burden hour per response | Annual burden hours | Hourly cost per response | Annual cost |
|---|---|---|---|---|---|---|---|
| Physical and Technology Infrastructure. | 3,400 | once ..... | 50 | 1 | 1 | 0 | 0 |
| Potential uses of federal and local resources. | 3,400 | once ..... | 50 | 1 | 1 | ..... | ..... |
| Totals ..... | 3,400 | once ..... | 150 | 3 | 3 | 0 | 0 |

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 12, 2015.

**Camille E. Acevedo,**

*Associate General Counsel for Legislation and Regulations.*

[FR Doc. 2015–11806 Filed 5–14–15; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5828–N–20]**

## Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

**FOR FURTHER INFORMATION CONTACT:** Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

**SUPPLEMENTARY INFORMATION:** In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–8873; COE: Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street NW., Washington, DC 20314; (202) 761–5542; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management; Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: May 7, 2015.

**Brian P. Fitzmaurice,**

*Director, Division of Community Assistance, Office of Special Needs Assistance Programs.*

**Title V, Federal Surplus Property Program Federal Register Report for 05/15/2015**

**Suitable/Available Properties**

*Building*

District of Columbia

49 L Street
49 L St. SE
Washington DC 20003
Landholding Agency: GSA
Property Number: 54201520003
Status: Excess
GSA Number: DC–496–1
Comments: 32,013 sq. ft.; storage; 67+ mons. vacant; poor condition; roof leaks; extensive structural repairs needed; cracks in walls; contamination; est. repair cost $4,000,000; contact GSA for more info.

Indiana

2 Buildings
2828 Madison Avenue
Anderson IN 64014
Landholding Agency: COE
Property Number: 31201520002
Status: Excess
Directions: 1LT Charles Waples U.S. Army Reserve Center; Admin Bldg. 11,525 sq. ft.; OMS 2,998 sq. ft.
Comments: off-site removal only; 59+ yrs. old; Army Reserve Center; fair condition; asbestos; contact COE for more information.

Montana

Jackson Residence, Bldg. #1016
1000 Warm Springs Road
Jackson MT 59736
Landholding Agency: Agriculture
Property Number: 15201520024
Status: Unutilized
Comments: 90+ yrs. old; 1,231 sq. ft.; 9+ mos. vacant; residential; extensive water damage & mold contamination throughout the interior; require demolition to remediation; contact Agric. for more information.

Residential Garage W/1032
Infra #1500
Ant Flat Road
Eureka MT 95501
Landholding Agency: Agriculture
Property Number: 15201520025
Status: Excess
Comments: off-site removal only; 61+ yrs. old; 491 sq. ft.; storage; contact Agriculture for more information.

2-Bedroom Family Dwelling
Infra #1032
Ant Flat Road
Eureka MT 95501
Landholding Agency: Agriculture
Property Number: 15201520026
Status: Excess
Comments: off-site removal; 64+ yrs. old; 1,004 sq. ft.; residential; 30+ mos. vacant; experience extensive flood; damage which caused significant mold damage; contact Agriculture for more information.

Wyoming

2 Buildings
Cheyenne Naval Reserve Center
4700 Ocean Loop Drive
Cheyenne WY 82009
Landholding Agency: GSA
Property Number: 54201520009
Status: Surplus
GSA Number: 7–G–WY–0542–AC
Directions: Previously reported under HUD property number 54200510015. The property was originally conveyed from the GSA to the Wyoming Coalition of Homeless as a PBC for homeless use. Grantee unable to continue to use the property for homeless purposes. The title reverted to the Government.
Comments: 36+yrs. old, building (11,858 sq. ft.); shed (613 sq. ft.); 12+ mos. vacant; contact GSA for more information.

**Suitable/Unavailable Properties**

*Building*

California

Southern Parcel-Alameda Fed Ct
620 Central Avenue
Alameda CA 94501
Landholding Agency: GSA
Property Number: 54201510008
Status: Unutilized
GSA Number: 9–G–CA–1604–AB
Directions: Building #7 (4,000 sq. ft.); Building #3 (5,000 sq.ft.); Correction: Published as Suitable/Available in the March 13, 2015 FR; however, there is existing Federal need. This property is Suitable/Unavailable until further notification is received by GSA.
Comments: 73+yrs.old; office; auditorium; wood; #7 fair condition; #3 leaky roof; sits on 3.899 acres; parking lot; term use up to 4 yrs.; contact GSA for more info.

**Unsuitable Properties**

*Building*

Alabama

3 Buildings
Marshall Space Flight Center
Marshall Space Flight AL 35812
Landholding Agency: NASA
Property Number: 71201520001
Status: Underutilized
Directions: 4679 Electrical Equipment Building; 4642 Center Activities; 4703 Storage Building
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

Missouri

Table Rock Lake Project
40263 State Hwy 86
Barry County MO 62625
Landholding Agency: COE
Property Number: 31201520004
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

South Carolina

Building 216
1630 Avenue A South
N. Charleston SC 29405
Landholding Agency: Navy
Property Number: 77201520007
Status: Unutilized
Directions: Disposal Agency: Navy; Land Holding Agency: AF
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

[FR Doc. 2015–11457 Filed 5–14–15; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5835–N–06]**

## 60-Day Notice of Proposed Information Collection: Application for FHA Insured Mortgages

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* July 14, 2015.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

**FOR FURTHER INFORMATION CONTACT:** Graham Mayfield, Reports The office of Single Family, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Graham.B.Mayfield@Hud.gov.* Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms.Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

**A. Overview of Information Collection**

*Title of Information Collection:* Application for FHA Insured Mortgage.

*OMB Approval Number:* 2502–0059.

*Type of Request:* Revision.

*Form Number:* HUD–92900–A, HUD–92900–B, HUD–92900–LT, HUD–92561, Model Notice for Informed Consumer Choice Disclosure, and Model Pre-Insurance Review/Checklist.

*Description of the need for the information and proposed use:* Specific forms and related documents are needed to determine the eligibility of the borrower and proposed mortgage transaction for FHA's insurance endorsement. Lenders seeking FHA's insurance prepare certain forms to collect data.

*Respondents:* Regulatory or compliance.

*Estimated Number of Respondents:* 11,604.

*Estimated Number of Responses:* 4,743,185.

*Frequency of Response:* 1 document per loan.

*Average Hours per Response:* 90 minutes.

*Total Estimated Burdens:* 534,931.

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following: Form HUD 92900–A has been revised as follows:

**Page 1, Part II, Lender/Mortgagee Certification, 21; Statements B and E revised as follows:**

B. (1) The information contained in the initial Uniform Residential Loan Application and this Addendum was obtained from the Borrower by an employee of the undersigned lender/mortgagee or its duly authorized agent and is to the best of lender/mortgagee's knowledge true, complete and accurate as of the date the Borrower provided the information to the undersigned lender/mortgagee or its duly authorized agent.

(2) The information contained in the final Uniform Residential Loan Application, which was signed by the Borrower at the time of settlement, was obtained by an employee of the undersigned lender/mortgagee or its duly authorized agent is to the best of lender/mortgagee's knowledge true, complete and accurate as of the date verified by the lender/mortgagee.

E. (1) To the best of my knowledge, neither I nor any parties to this transaction are suspended, debarred, under a limited denial of participation, or otherwise restricted under 2 CFR part 2424, or under similar procedures of any other federal agency.

(2) The lender/mortgagee involved in this transaction is not suspended, debarred, under a limited denial of participation, or otherwise restricted under 2 CFR part 2424 or 24 CFR part 25, or under similar procedures of any other federal agency.

Part V, Borrower Certification, 25; Added the following:

(2) Occupancy: HUD Only

I, the Borrower or Co-Borrower will occupy the property within 60 days of signing the security instrument, and intend to continue occupancy for at least one year. I do not intend to occupy the property as my primary residence.

Direct Endorsement Approval for a HUD FHA-Insured Mortgage; Added:

This mortgage was rated as an ''accept'' or ''approve'' by FHA's TOTAL Mortgage Scorecard and the undersigned Direct Endorsement underwriter certifies that I have personally reviewed and underwritten the appraisal according to standard FHA requirements.

_____

Direct Endorsement Underwriter Signature

_____

CHUMS ID Number

This mortgage was rated as a ''refer'' by a FHA's TOTAL Mortgage Scorecard, or was manually underwritten by a Direct Endorsement underwriter. As such, the undersigned Direct Endorsement Underwriter certifies that I have personally reviewed the appraisal report (if applicable), credit application, and all associated documents used in underwriting this mortgage. I further certify that:

I have approved this loan and my Final Underwriting Decision was made having exercised the required level of Care and Due Diligence;

I have performed all Specific Underwriter Responsibilities for Underwriters and my underwriting of the borrower's Credit and Debt, Income, Qualifying Ratios and Compensating Factors, if any, and the borrower's DTI with Compensating Factors, if any, are within the parameters established by FHA and the borrower has assets to satisfy any required down payment and closing costs of this mortgage; and

I have verified the Mortgage Insurance Premium and Mortgage Amount are true and correct and this loan is in an amount that is permitted by FHA for this loan type, property type, and geographic area.

_____

Direct Endorsement Underwriter Signature

_____

CHUMS ID Number

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 12, 2015.

**Laura M. Marin,**

*Associate General Deputy Assistant Secretary for Housing—Associate Deputy Federal Housing Commissioner.*

[FR Doc. 2015–11807 Filed 5–14–15; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[156A2100DD/AAKC001030/ A0A501010.999900 253G]**

### Tribal Education Department Grant Program

**AGENCY:** Bureau of Indian Education, Interior.

**ACTION:** Notice of availability and request for proposals.

**SUMMARY:** The Bureau of Indian Education (BIE) announces the

availability of grants to tribes and their tribal education departments for projects identified at 25 U.S.C. 2020. This notice invites tribes with BIE-funded schools on or near Indian lands to submit grant proposals.

**DATES:** Grant proposals must be received by June 15, 2015, at 5:00 p.m. Eastern Standard Time. The BIE will hold pre-application training sessions, see **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** Complete details on requirements for proposals and the evaluation and selection process can be found on the BIE Web site at this address: *www.bie.edu.* Submit grant applications to: Bureau of Indian Education, Attn: Ms. Wendy Greyeyes, 1849 C Street NW., MS–4657–MIB, Washington, DC 20240. Email submissions will be accepted at this address: *wendy.greyeyes@bie.edu.* See the **SUPPLEMENTARY INFORMATION** section of this notice for directions on email submissions.

**FOR FURTHER INFORMATION CONTACT:** Ms. Wendy Greyeyes, Bureau of Indian Education, Office of the BIE Director, (202) 208–5810; *wendy.greyeyes@bie.edu.*

**SUPPLEMENTARY INFORMATION:** The Secretary of the Interior, through BIE, may solicit grant proposals from federally recognized tribes and their tribal education departments (TEDs) for projects defined by 25 U.S.C. 2020. These funds will support the program goals for the following areas to promote tribal education capacity building within Indian reservations to:

- Provide for the development and enforcement of tribal educational codes, including tribal educational policies and tribal standards applicable to curriculum, personnel, students, facilities, and support programs;
- Facilitate tribal control in all matters relating to the education of Indian children on reservations (and on former Indian reservations in Oklahoma); and
- Provide for the development of coordinated educational programs (including all preschool, elementary, secondary, and higher or vocational educational programs funded by tribal, Federal, or other sources) on reservations (and on former Indian reservations in Oklahoma) by encouraging administrative support of all BIE-funded educational programs and encouraging tribal cooperation and coordination with entities carrying out all educational programs receiving financial support from other Federal agencies, State agencies, or private entities.

Grant awards will range from $25,000 to $150,000 per fiscal year depending on the number of projects, number of educational programs impacted, project design and expected outcomes. Subject to the availability of appropriated funds, a grant provided under 25 U.S.C. 2020 shall be provided for a period of three years. If the performance of a grant recipient is satisfactory to the Secretary, the grant may be renewed for an additional two-year term. As defined by 25 U.S.C. 2020, top priority will be given to proposals that meet the following:

- Serve three or more separate BIE-funded schools;
- Provide coordinating services and technical assistance to all relevant BIE-funded schools;
- Plan to monitor and audit grant funds by or through the TED; and/or
- Provide a plan and schedule that:
  - ○ Provides for:
    - ▪ The assumption, by the TED, of all assets and functions of the BIE agency office associated with the tribe, to the extent the assets and functions relate to education; and
    - ▪ the termination by BIE of such functions and office at the time of such assumption; and
  - ○ provides that the assumption will occur over the term of the grant, unless mutually agreeable to the tribal governing body and the Assistant Secretary—Indian Affairs, the period in which such assumption is to occur may be modified, reduced, or extended after the initial year of the grant.

BIE is seeking proposals from tribes that support the development of TEDs to improve educational outcomes for students and improve efficiencies and effectiveness in the operation of BIE-funded schools. Each proposal must include a project narrative, a budget narrative, and a work plan outline. Grant recipients must submit quarterly budget updates and an annual report at the end of each project year to ensure that the TED fulfills the obligations of the grant. Complete details on requirements for proposals and the evaluation and selection process can be found on the BIE Web site at the address in the **ADDRESSES** section of this notice. In addition, BIE will hold pre-grant proposal training at several sites:

BIE PRE-GRANT PROPOSAL TRAINING

| Date | Time | Location |
|---|---|---|
| Monday, May 18, 2015 | 11 a.m. to 2 p.m. (Local Time) | Webinar Session (Washington, DC): To register for this session, go to: *https://dcma100.webex.com/dcma100/k2/j.php?MTID=t483049bb290ad1f0c1fa16ea0d979b83.* |
| Wednesday, May 27, 2015 | 9 a.m. to 3 p.m. (Local Time) | Albuquerque, New Mexico. More detailed information is available at *www.bie.edu.* |
| Monday, June 1, 2015 | 9 a.m. to 3 p.m. (Local Time) | Bismarck, North Dakota. More detailed information is available at *www.bie.edu.* |

The grant proposal is due June 15, 2015, at 5:00 p.m. Eastern Time. The proposal should be packaged for delivery to permit timely arrival and sent or hand-delivered to the address in the **ADDRESSES** section of this notice.

Fax applications will NOT be accepted. Email submissions will be accepted at the address in the **ADDRESSES** section of this notice. Email submissions are limited to attachments compatible with Microsoft Office Word 2007 or later or files with a .pdf file extension. Emailed submissions must not exceed 3MB total in size.

Proposals submitted by Federal Express or Express Mail should be sent two or more days before the closing date to ensure receipt by the deadline. The proposal package should be sent to the address shown in the **ADDRESSES** section of this notice. The tribe is solely responsible for ensuring that its proposal arrives in a timely manner.

Dated: May 11, 2015.

**Lawrence S. Roberts,**

*Principal Deputy Assistant Secretary—Indian Affairs.*

[FR Doc. 2015–11658 Filed 5–14–15; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[156A2100DD/AAKC001030/ A0A501010.999900 253G]**

### Draft Environmental Impact Statement for the Proposed Aiya Solar Project, Clark County, Nevada

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of Availability.

**SUMMARY:** In accordance with the National Environmental Policy Act (NEPA), the Bureau of Indian Affairs (BIA), as the lead Federal agency, with the Bureau of Land Management (BLM), the Environmental Protection Agency (EPA), U.S. Fish and Wildlife Service (USFWS), and the Moapa Band of Paiute Indians (Tribe) as Cooperating Agencies, has prepared a draft environmental impact statement (DEIS) for the proposed Aiya Solar Project on the Moapa River Indian Reservation (Reservation) in Clark County, Nevada. This notice announces that the DEIS is now available for public review and that BIA will hold public meetings to solicit comments on the DEIS.

**DATES:** The date and locations of the public meetings will be announced at least 15 days in advance through notices in the following local newspapers: Las Vegas Sun, Las Vegas Review Journal and the Moapa Valley Progress and on the following Web site: *www.AiyaSolarProjectEIS.com.* In order to be fully considered, written comments on the DEIS must arrive no later than 45 days after EPA publishes its Notice of Availability in the **Federal Register**.

**ADDRESSES:** You may mail, email, hand deliver or telefax written comments to Mr. Chip Lewis, Acting Regional Environmental Protection Officer, BIA Western Regional Office, Branch of Environmental Quality Services, 2600 North Central Avenue, 4th Floor Mail Room, Phoenix, Arizona 85004–3008; fax (602) 379–3833; email: *chip.lewis@bia.gov.* The DEIS will be available for review at: BIA Western Regional Office, 2600 North Central Avenue, 12th Floor, Suite 210, Phoenix, Arizona; BIA Southern Paiute Agency, 180 North 200 East, Suite 111, St. George, Utah; and the BLM Southern Nevada District Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada. The DEIS is also available on line at: *www.AiyaSolarProjectEIS.com.*

To obtain a compact disk copy of the DEIS, please provide your name and address in writing or by voicemail to Mr. Chip Lewis or Mr. Garry Cantley. Their contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual paper copies of the DEIS will be provided only upon request.

**FOR FURTHER INFORMATION CONTACT:** Mr. Chip Lewis, BIA Western Regional Office, Branch of Environmental Quality Services, 2600 North Central Avenue, Phoenix, Arizona 85004–3008, telephone (602) 379–6782; or Mr. Garry Cantley at (602) 379–6750.

**SUPPLEMENTARY INFORMATION:** The proposed Federal action, taken under 25 U.S.C. 415, is BIA's approval of a solar energy ground lease and associated agreements entered into by the Tribe with Aiya Solar Project, LLC (Aiya Solar or Applicant), a wholly owned subsidiary of First Solar, Inc. (First Solar), to provide for construction and operation of an up-to 100 megawatt (MW) alternating current solar photovoltaic (PV) electricity generation facility located entirely on the Reservation and specifically on lands held in trust by BIA for the Tribe. The proposed 230 kilovolt (kV) generation-tie transmission line required for interconnection would be located on Tribal lands, private lands and Federal lands administered and managed by BLM. The Applicant has accordingly requested that BIA and BLM additionally approve right-of-ways (ROWs) authorizing the construction and operation of the transmission line. Together, the proposed solar energy facility, transmission line, and other associated facilities make up the proposed Aiya Solar Project (Project).

The Project would be located in Township 14 South, Range 66 East, Sections 29, 30, 31, and 32 Mount Diablo Meridian, Nevada. The generation facility would generate electricity using PV panels. Also included would be inverters, a collection system, an on-site substation to step-up the voltage to transmission level voltage at 230 kV, an operations and maintenance building, and other related facilities. A single overhead 230 kV generation-tie transmission line, approximately 1.5 to 3 miles long, would connect the solar project to NV Energy's Reid-Gardner 230kV substation through a point northeast of the existing Reid-Gardner substation where a new NV Energy collector station would be built in the future.

Construction of the Project is expected to take approximately 12 to 15 months. The Applicant is expected to operate the energy facility for 30 years, with two options to renew the lease for an additional 10 years, if mutually acceptable to the Tribe and Applicant. During construction, the PV panels will be placed on top of fixed-tilt and/or single-axis tracking mounting systems that are set on steel posts embedded in the ground. Other foundation design techniques may be used depending on the site topography and conditions. No water will be used to generate electricity during operations. Water will be needed during construction for dust control and a minimal amount will be needed during operations for landscape irrigation and administrative and sanitary water use on site. The water supply required for construction of the Project would be leased from the Tribe and would be provided via a new temporary intake installed in the Muddy River and a new temporary above-ground pipeline approximately two miles in length. Operational water would be provided through a tap into an existing water pipeline that crosses the solar site. Access to the Project will be provided via State Highway 168.

The purposes of the Project are to: (1) Provide a long-term, diverse, and viable economic revenue base and job opportunities for the Tribe; (2) help Nevada and neighboring states to meet their state renewable energy needs; and (3) allow the Tribe, in partnership with the Applicant, to optimize the use of the lease site while maximizing the potential economic benefit to the Tribe.

The BIA and BLM will use the EIS to make decisions on the land lease and ROW applications under their respective jurisdiction. The EPA may use the document to make decisions under its authorities. The Tribe may use the EIS to make decisions under its Tribal Environmental Policy Ordinance. The USFWS may use the EIS to support its decision under the Endangered Species Act.

*Directions for Submitting Comments:* Please include your name, return address and the caption: ''DEIS Comments, Proposed Aiya Solar Project'', on the first page of your written comments.

*Public Comment Availability:* Written comments, including names and addresses of respondents will be available for public review at the BIA mailing addresses shown in the **ADDRESSES** section during regular business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal

identifying information from public review, we cannot guarantee that we will be able to do so.

**Authority:** This notice is published in accordance with section 1503.1 of the Council on Environmental Quality regulations (40 CFR part 1500 *et seq.*) and the Department of the Interior Regulations (43 CFR part 46) implementing the procedural requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and in accordance with the exercise of authority delegated to the Assistant Secretary—Indian Affairs by part 209 of the Department Manual.

Dated: May 1, 2015.

**Kevin Washburn,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2015–11298 Filed 5–14–15; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[LLNVC02000 L57000000.BX0000; 241A; MO# 4500077944]**

## Notice of Temporary Closures of Public Land in Washoe County, Nevada

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** As authorized under the provisions of the Federal Land Policy and Management Act of 1976 and relevant regulations, certain public land near Stead, Nevada, will be temporarily closed to all public use to provide for public safety during the 2015 Reno Air Racing Association Pylon Racing Seminar and the Reno National Championship Air Races.

**DATES:** Temporary closure periods are June 17 through June 20, 2015, and September 16 through September 20, 2015.

**FOR FURTHER INFORMATION CONTACT:** Leon Thomas, 775–885–6000, email: *l70thoma@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** This closure applies to all public use, including pedestrian use and vehicles. The public lands affected by this closure are described as follows:

**Mount Diablo Meridian**

T. 21 N., R. 19 E.,
Sec. 8, E½E½, NW¼NE¼;
Sec. 16, SW¼SW¼NE¼, NW¼, W½SE¼.

The area described contains 450 acres, more or less, in Washoe County, Nevada.

The closure notice and map of the closure area will be posted at the BLM Carson City District Office, 5665 Morgan Mill Road, Carson City, Nevada and on the BLM Web site: *http://www.blm.gov/nv/st/en/fo/carsoncity_field.html.* Roads leading into the public lands under the closure will be posted to notify the public of the closure. Under the authority of Section 303(a) of the Federal Lands Policy and Management Act of 1976 (43 U.S.C. 1733(a)), 43 CFR 8360.9–7 and 43 CFR 8364.1, the Bureau of Land Management will enforce the following rules in the area described above: All public use, whether motorized, on foot, or otherwise, is prohibited.

*Exceptions:* Closure restrictions do not apply to event officials, medical and rescue personnel, law enforcement, and agency personnel monitoring the events.

*Penalties:* Any person who fails to comply with the closure orders is subject to arrest and, upon conviction, may be fined not more than $1,000 and/or imprisonment for not more than 12 months under 43 CFR 8360.0–7. Violations may also be subject to the provisions of Title 18, U.S.C. 3571 and 3581.

**Authority:** 43 CFR 8360.0–7 and 8364.1.

**Leon Thomas,**

*Field Manager, Sierra Front Field Office.*

[FR Doc. 2015–11682 Filed 5–14–15; 8:45 am]

**BILLING CODE 4310–HC–P**

## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[15X L1109AF LLUT920000 L13200000.EL0000, UTU–77114]**

## Notice of Federal Competitive Coal Lease Sale, Utah

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the United States Department of the Interior, Bureau of Land Management (BLM) Utah State Office will offer certain coal resources described below as the Flat Canyon Tract (UTU–77114) in Sanpete County, Utah, for competitive sale by sealed bid, in accordance with the Federal regulations for competitive lease sale notices and the Mineral Leasing Act of 1920, as amended and supplemented.

**DATES:** The lease sale will be held at 1:00 p.m. on June 17, 2015. Sealed bids must be sent by certified mail, return receipt requested, to the Collections Officer, BLM Utah State Office or be hand delivered to the public room Contact Representatives, BLM Utah State Office at the address indicated below, and must be received on or before 10:00 a.m. on June 17, 2015. Any bid received after the time specified will not be considered and will be returned.

The BLM public room Contact Representative will issue a receipt for each hand-delivered sealed bid. The outside of the sealed envelope containing the bid must clearly state that the envelope contains a bid for Coal Lease Sale UTU–77114 and is not to be opened before the date and hour of the sale.

**ADDRESSES:** The lease sale will be held in the Monument Conference Room at the following address: BLM-Utah State Office, Suite 500, 440 West 200 South, Salt Lake City, Utah 84101. Sealed bids can be hand delivered to the BLM public room Contact Representative or mailed to the Collections Officer, BLM Utah State Office, at the address given above.

**FOR FURTHER INFORMATION CONTACT:** Contact Jeff McKenzie, 440 West 200 South, Suite 500 Salt Lake City, Utah 84101–1345 or telephone 801–539–4038. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to leave a message or question for the above individual. The FIRS is available 24 hours a day, 7 days a week. Replies are provided during normal business hours.

**SUPPLEMENTARY INFORMATION:** This coal lease sale is being held in response to a lease by application (LBA) submitted by Canyon Fuel Company, LLC. to the BLM on March 18, 1998. The successful bidder must pay to the BLM the cost BLM incurs regarding the publishing of this sale notice. If there is no successful bidder, the applicant will be responsible for all publishing costs.

The coal resources to be offered consist of all reserves recoverable by underground methods available in the following-described lands located in Sanpete County, Utah, approximately 10 miles southeast of Scofield, Utah, under both private and public surface.

**Salt Lake Meridian**

T. 13 S., R.6 E.,
Sec. 21, lots 1 to 4, inclusive, E1/2NE1/4, and E1/2SE1/4;

Sec. 28, lots 1 to 8, inclusive, S1/2NW1/4, and SW1/4;
Sec. 33, NE1/4, E1/2NW1/4, NW1/4NW1/4, E1/2SW1/4, SW1/4SW1/4, and SE1/4.
T. 14 S., R. 6 E.,
Sec. 4;
Sec. 5.

Containing approximately 2,692.16 acres.

The tract is adjacent to the Skyline mine which contains other federal coal leases. The coal beds contained in this tract are under an average of 1,700 feet cover from the surface. The coal in the Flat Canyon tract has two economical coal beds; the Lower O'Conner B and the Flat Canyon beds. The minable portions of these coal beds are approximately 6 to 14 feet in thickness. The tract contains approximately 42 million tons of recoverable high-volatile B bituminous coal. The coal quality is based on an ''as received basis'' as follows: 12,400 Btu/lb., 5.80 percent moisture, 7.1 percent ash, 42.8 percent volatile matter, 43.8 percent fixed carbon and 0.50 percent sulfur.

The tract will be leased to the qualified bidder of the highest cash amount provided that the high bid meet or exceeds the BLM's estimate of the fair market value (FMV) of the tract. The minimum bid for the tract is $100 per acre or fraction thereof. No bid that is less than $100 per acre, or fraction thereof, will be considered. The minimum bid is not intended to represent FMV. The FMV of the tract will be determined by the Authorized Officer after the sale.

The BLM held a public hearing and requested comments on the Environmental Impact Statement (EIS) and the FMV of the Dry Canyon Tract on June 21, 2001. The BLM/U.S. Forest Service (USFS) prepared a Final Environmental Impact Statement and a Record of Decision on January 3, 2002. No appeals of the BLM decision to lease were filed during the appeal period. The USFS issued consent to lease on February 4, 2013. On December 24, 2014, the Governor of the State of Utah recommended proceeding with this lease sale.

The lease that may be issued as a result of this offering will provide for payment of an annual rental of $3 per acre or fraction thereof, and a royalty of 8 percent of the value of the coal produced by underground mining methods. The value of the coal will be determined in accordance with 30 CFR 1206.250.

The detailed statement for the offered tract, including bidding instructions and sales procedures under 43 CFR 3422.3–2, and the terms and conditions of the proposed coal lease, is available from the BLM-Public Room, Utah State Office, Suite 500, 440 West 200 South, Salt Lake City, Utah 84101. Case file documents, UTU–77114, are available for inspection during normal business hours in the BLM-Public Room, Suite 500.

Approved:

**Jenna Whitlock,**

*Acting State Director.*

[FR Doc. 2015–11845 Filed 5–14–15; 8:45 am]

**BILLING CODE 4310–DQ–P**

---

## DEPARTMENT OF THE INTERIOR

### Office of Natural Resources Revenue

**[Docket No. ONRR–2011–0020; DS63610000 DR2PS0000.CH7000 156D0102R2]**

### Agency Information Collection Activities: Royalty and Production Reporting—-OMB Control Number 1012–0004; Comment Request

**AGENCY:** Office of Natural Resources Revenue (ONRR), Interior.

**ACTION:** Notice of extension.

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), ONRR is inviting comments on a collection of information request that we will submit to the Office of Management and Budget (OMB) for review and approval of the paperwork requirements in the regulations under title 30, *Code of Federal Regulations* (CFR), parts 1210 and 1212. There are three forms associated with this information collection.

**DATES:** Submit written comments on or before July 14, 2015.

**ADDRESSES:** You may submit comments on this ICR to ONRR by using one of the following three methods (please reference ''ICR 1012–0004'' in your comments):

1. Electronically go to *http://www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter ''ONRR–2011–0020'' and then click ''Search.'' Follow the instructions to submit public comments. ONRR will post all comments.

2. Mail comments to Mr. Luis Aguilar, Regulatory Specialist, ONRR, P.O. Box 25165, MS 61030A, Denver, Colorado 80225–0165.

3. Hand-carry or mail comments, using an overnight courier service, to ONRR. Our courier address is Building 85, Room A–614, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225.

**FOR FURTHER INFORMATION CONTACT:** For questions on technical issues, contact Lee-Ann Martin, Reporting and Solid Minerals Services, ONRR, telephone (303) 231–3313, or email *leeann.martin@onrr.gov.* For other questions, contact Mr. Luis Aguilar, telephone (303) 231–3418, or email *luis.aguilar@onrr.gov.* You may also contact Mr. Aguilar to obtain copies, at no cost, of (1) the ICR, (2) any associated form, and (3) the regulations that require us to collect the information.

**SUPPLEMENTARY INFORMATION:**

### I. Abstract

The Secretary of the United States Department of the Interior is responsible for collecting royalties from lessees who produce minerals from leased Federal and Indian lands and the Outer-Continental Shelf (OCS). The Secretary's responsibility, under various laws, is to manage mineral resource production from Federal and Indian lands and the OCS, collect the royalties and other mineral revenues due, and distribute the funds collected under those laws. ONRR performs the royalty management functions for the Secretary.

We have posted those laws pertaining to mineral leases on Federal and Indian lands and the OCS at *http://www.onrr.gov/Laws_R_D/PubLaws/default.htm.*

The Secretary also has a trust responsibility to manage Indian lands and seek advice and information from Indian beneficiaries. ONRR performs the minerals revenue management functions and assists the Secretary in carrying out the Department's trust responsibility for Indian lands. When a company or an individual enters into a lease to explore, develop, produce, and dispose of minerals from Federal or Indian lands, that company or individual agrees to pay the lessor a share in an amount or value of production from the leased lands. The lessee, or his designee, is required to report various kinds of information to the lessor relative to the disposition of the leased minerals.

The ONRR financial accounting system is an integrated computer system that includes royalty, rental, bonus, and other payments; sales volumes and values; and royalty values as submitted by reporters. In the system, ONRR compares production volumes with royalty volumes to verify that reporters reported and paid proper royalties for the minerals produced. Additionally, we share the data electronically with the Bureau of Safety and Environmental Enforcement, Bureau of Land Management, Bureau of Indian Affairs, and Tribal and State governments so they can perform their lease management responsibilities.

We use the information collected in this ICR to ensure that royalty is appropriately paid, based on accurate

production accounting on oil, gas, and geothermal resources produced from Federal and Indian leases. The requirement to report accurately and timely is mandatory. Please refer to the chart for all reporting requirements and associated burden hours.

*Royalty Reporting*

The regulations require payors (reporters) to report and to remit royalties on oil, gas, and geothermal resources produced from leases on Federal and Indian lands. The following form is used for royalty reporting:

*Form ONRR–2014, Report of Sales and Royalty Remittance.* Reporters submit this form monthly to report royalties on oil, gas, and geothermal leases, certain rents, and other lease-related transactions, such as transportation and processing allowances, lease adjustments, and quality and location differentials.

*Production Reporting*

The regulations require operators (reporters) to submit production reports if they operate a Federal or Indian onshore or offshore oil and gas lease, or Federally approved unit or communitization agreement. The ONRR financial accounting system tracks minerals produced from Federal and Indian lands, from the point of production to the point of disposition, or royalty determination, and/or point of sale. The reporters use the following forms for production accounting and reporting:

*Form ONRR–4054, Oil and Gas Operations Report (OGOR).* Reporters submit this form monthly for all production reporting for Outer Continental Shelf, Federal, and Indian leases. ONRR compares the production information with sales and royalty data that reporters submit on Form ONRR–2014 to ensure that the latter reported and paid the proper royalties on the oil and gas production to ONRR. ONRR uses the information from OGOR parts A, B, and C to track all oil and gas from the point of production to the point of first sale, or other disposition.

*Form ONRR–4058, Production Allocation Schedule Report (PASR).* Reporters submit this form monthly. The facility operators manage the facilities and measurement points where they commingle the production from an offshore Federal lease or metering point with production from other sources before they measure it for royalty determination. ONRR uses the data to determine if the operators reported the correct royalty-bearing volumes on the OGOR.

*OMB Approval*

We will request OMB approval to continue to collect this information. If ONRR does not collect this information, this would limit the Secretary's ability to discharge fiduciary duties and may also result in loss of royalty payments. We protect the proprietary information that we receive and do not collect items of a sensitive nature. It is mandatory that the reporters submit Forms ONRR–2014, ONRR–4054, and ONRR–4058.

**II. Data**

*Title:* 30 CFR parts 1210 and 1212, Royalty and Production Reporting.

*OMB Control Number:* 1012–0004.

*Bureau Form Number:* Forms ONRR–2014, ONRR–4054, and ONRR–4058.

*Frequency:* Monthly.

*Estimated Number and Description of Respondents:* 3,870 oil, gas, and geothermal reporters.

*Estimated Annual Reporting and Recordkeeping ''Hour'' Burden:* 337,933 hours.

We have changed our estimates of the number of respondents due to updated data.

We have not included in our estimates certain requirements performed in the normal course of business, considered as usual and customary. We display the estimated annual burden hours by CFR section and paragraph in the following chart.

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS

| 30 CFR Part 1210 | Reporting and recordkeeping requirement | Hour burden | Average number of annual responses | Annual burden hours |
|---|---|---|---|---|
| **30 CFR 1210—FORMS AND REPORTS Subpart B—Royalty Reports—Oil, Gas, and Geothermal Resources** | | | | |
| 1210.52(a) and (b) ..... | 1210.52 What royalty reports must I submit? | Form ONRR–2014 | | |
| | You must submit a completed Form ONRR–2014, Report of Sales and Royalty Remittance, to ONRR with: | Electronic * (approximately 99 percent) | | |
| | (a) All royalty payments; and | 3 min ..... | 4,688,216 | 234,411 |
| | (b) Rents on nonproducing leases, where specified in the lease. | Manual * (approximately 1 percent) | | |
| 1210.53(a), (b), and (c) ..... | 1210.53 When are my royalty reports and payments due? (a) Completed Forms ONRR–2014 for royalty payments and the associated payments are due by the end of the month following the production month (see also § 1218.50). (b) Completed Forms ONRR–2014 for rental payments, where applicable, and the associated payments are due as specified by the lease terms (see also § 1218.50). (c) You may submit reports and payments early. | 7 min ..... | 47,356 | 5,525 |
| 1210.54(a), (b), and (c) ..... | 1210.54 Must I submit this royalty report electronically? (a) You must submit Form ONRR–2014 electronically unless you qualify for an exception under § 1210.55(a). (b) You must use one of the following electronic media types, unless ONRR instructs you differently * * * | | | |

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

| 30 CFR Part 1210 | Reporting and recordkeeping requirement | Hour burden | Average number of annual responses | Annual burden hours |
|---|---|---|---|---|
| | (c) Refer to our electronic reporting guidelines in the ONRR *Minerals Revenue Reporter Handbook,* for the most current reporting options, instructions, and security measures. The handbook may be found on our Internet Web site or you may call your ONRR customer service representative * * *<br>* * * * * | | | |
| Subtotal for Royalty Reporting | | | 4,735,572 | 239,936 |
| **Subpart C—Production Reports—Oil and Gas** | | | | |
| 1210.102(a)(1)(i) and (ii) .....<br>1210.102(a)(2)(i) and (ii) ..... | 1210.102 What production reports must I submit?<br>(a) Form ONRR–4054, Oil and Gas Operations Report. If you operate a Federal or Indian onshore or OCS oil and gas lease or federally approved unit or communitization agreement that contains one or more wells that are not permanently plugged or abandoned, you must submit Form ONRR–4054 to ONRR:<br>(1) You must submit Form ONRR–4054 for each well for each calendar month, beginning with the month in which you complete drilling, unless:<br>(i) You have only test production from a drilling well; or<br>(ii) The ONRR tells you in writing to report differently.<br>(2) You must continue reporting until:<br>(i) The Bureau of Land Management (BLM) or [Bureau of Safety and Environmental Enforcement] approves all wells as permanently plugged or abandoned or the lease or unit or communitization agreement is terminated; and<br>(ii) You dispose of all inventory. | Burden hours covered under 1210.104(a) and (b). | | |
| 1210.102(b)(1) .....<br>1210.102(b)(2)(i)–(vi) ..... | (b) Form ONRR–4058, Production Allocation Schedule Report. If you operate an offshore facility measurement point (FMP) handling production from a Federal oil and gas lease or federally approved unit agreement that is commingled (with approval) with production from any other source prior to measurement for royalty determination, you must file Form ONRR–4058.<br>(1) You must submit Form ONRR–4058 for each calendar month beginning with the month in which you first handle production covered by this section.<br>(2) Form ONRR–4058 is not required whenever all of the following conditions are met:<br>(i) All leases involved are Federal leases;<br>(ii) All leases have the same fixed royalty rate;<br>(iii) All leases are operated by the same operator;<br>(iv) The facility measurement device is operated by the same person as the leases/agreements;<br>(v) Production has not been previously measured for royalty determination; and<br>(vi) The production is not subsequently commingled and measured for royalty determination at an FMP for which Form ONRR–4058 is required under this part. | Burden hours covered under 1210.104(a) and (b). | | |
| 1210.103(a) and (b) ..... | 1210.103 When are my production reports due?<br>(a) The ONRR must receive your completed Forms ONRR–4054 and ONRR–4058 by the 15th day of the second month following the month for which you are reporting.<br>(b) A report is considered received when it is delivered to ONRR by 4 p.m. mountain time at the addresses specified in § 1210.105. Reports received after 4 p.m. mountain time are considered received the following business day. | Burden hours covered under 1210.104(a) and (b). | | |
| 1210.104(a), (b), and (c) ..... | 1210.104 Must I submit these production reports electronically? | Form ONRR–4054 (OGOR) | | |

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

| 30 CFR Part 1210 | Reporting and recordkeeping requirement | Hour burden | Average number of annual responses | Annual burden hours |
|---|---|---|---|---|
| | (a) You must submit Forms ONRR–4054 and ONRR–4058 electronically unless you qualify for an exception under § 1210.105 | Electronic * (approximately 99 percent) | | |
| | (b) You must use one of the following electronic media types, unless ONRR instructs you differently * * * | 1 min ..... | 5,688,962 | 94,816 |
| | (c) Refer to our electronic reporting guidelines in the ONRR *Minerals Production Reporter Handbook,* for the most current reporting options, instructions, and security measures. The handbook may be found on our Internet Web site or you may call your ONRR customer service representative * * * | Manual * (approximately 1 percent) | | |
| | * * * * * | 3 min ..... | 57,464 | 2,873 |
| | | Total OGOR | 5,746,426 | 97,689 |
| | | Form ONRR–4058 (PASR) | | |
| | | Electronic * (approximately 99 percent) | | |
| | | 1 min ..... | 17,820 | 298 |
| | | Manual * (approximately 1 percent) | | |
| | | 3 min ..... | 180 | 9 |
| | | Total PASR ... | 18,000 | 306 |
| **Subpart D—Special-Purpose Forms and Reports—Oil, Gas, and Geothermal Resources** | | | | |
| 1210.155 ..... | 1210.155 What reports must I submit for Federal onshore stripper oil properties?<br>(a) *General.* Operators who have been granted a reduced royalty rate by the Bureau of Land Management (BLM) under 43 CFR 3103.4–2 must submit Form ONRR–4377, Stripper Royalty Rate Reduction Notification, under 43 CFR 3103.4–2(b)(3).<br>* * * * * | Burden covered under OMB Control Number 1012–0005. | | |
| Subtotal for Production Reporting ..... | | | 5,764,426 | 97,996 |
| **PART 1212—RECORDS AND FILES MAINTENANCE<br>Subpart B—Oil, Gas and OCS Sulphur—General** | | | | |
| 1212.50 ..... | 1212.50 Required recordkeeping and reports .....<br>All records pertaining to offshore and onshore Federal and Indian oil and gas leases shall be maintained by a lessee, operator, revenue payor, or other person for 6 years after the records are generated unless the record holder is notified, in writing, that records must be maintained for a longer period * * *<br>[In accordance with 30 U.S.C. 1724(f), Federal oil and gas records must be maintained for 7 years from the date the obligation became due.] | Burden hours covered under 1210.54(a), (b), and (c); and 1210.104(a) and (b). | | |
| 1212.51(a) and (b) ..... | (a) *Records.* Each lessee, operator, revenue payor, or other person shall make and retain accurate and complete records necessary to demonstrate that payments of rentals, royalties, net profit shares, and other payments related to offshore and onshore Federal and Indian oil and gas leases are in compliance with lease terms, regulations, and orders * * * | Burden hours covered under 1210.54(a), (b), and (c); and 1210.104(a) and (b). | | |

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

| 30 CFR Part 1210 | Reporting and recordkeeping requirement | Hour burden | Average number of annual responses | Annual burden hours |
|---|---|---|---|---|
| | (b) Period for keeping records. Lessees, operators, revenue payors, or other persons required to keep records under this section shall maintain and preserve them for 6 years from the day on which the relevant transaction recorded occurred unless the Secretary notifies the record holder of an audit or investigation involving the records and that they must be maintained for a longer period * * * [In accordance with 30 U.S.C. 1724(f), Federal oil and gas records must be maintained for 7 years from the date the obligation became due.] | | | |
| Total for Royalty and Production Reporting | | | 10,499,998 | 337,933 |

* **Note:** ONRR consider each line of data as one response/report.

*Estimated Annual Reporting and Recordkeeping "Non-hour" Cost Burden:* We have not identified a "non-hour" cost burden associated with the collection of information.

**III. Request for Comments**

*Public Disclosure Statement:* The PRA (44 U.S.C. 3501 *et seq.)* provides that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current and valid OMB control number.

*Comments:* Before submitting an ICR to OMB, PRA Section 3506(c)(2)(A) requires each agency to "* * * provide 60-day notice in the **Federal Register** * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *." Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

The PRA also requires agencies to estimate the total annual reporting "non-hour cost" burden to respondents or recordkeepers resulting from the collection of information. If you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods that you use to estimate (1) major cost factors, including system and technology acquisition, (2) expected useful life of capital equipment, (3) discount rate(s), and (4) the period over which you incur costs. Capital and startup costs include, among other items, computers and software that you purchase to prepare for collecting information and monitoring, sampling, and testing equipment, and record storage facilities. Generally, your estimates should not include equipment or services purchased: (i) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Federal Government; or (iv) as part of customary and usual business, or private practices.

*Public Comment Policy:* ONRR will post all comments, including names and addresses of respondents at *http://www.regulations.gov.* Before including Personally Identifiable Information (PII), such as your address, phone number, email address, or other personal information in your comment(s), you should be aware that your entire comment (including PII) may be made available to the public at any time. While you may ask us, in your comment, to withhold PII from public view, we cannot guarantee that we will be able to do so.

Dated: May 11, 2015.

**Gregory J. Gould,**

*Director, Office of Natural Resources Revenue.*

[FR Doc. 2015–11792 Filed 5–14–15; 8:45 am]

BILLING CODE 4335–30–P

## DEPARTMENT OF THE INTERIOR

### Office of Natural Resources Revenue

**[Docket No. ONRR–2014–0002; DS63602000 DR2PS0000.PX8000 156D0102R2]**

### Agency Information Collection Activities: United States Extractive Industries Transparency Initiative (USEITI) Revenue Information Collection—OMB Control Number 1012—0NEW; Comment Request

**AGENCY:** Office of Natural Resources Revenue (ONRR), Interior.

**ACTION:** Notice for OMB approval.

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted this Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. This ICR covers the paperwork requirements for participation in the United States implementation of the Extractive Industries Transparency Initiative (USEITI). This notice also provides the public a second opportunity to comment on the paperwork burden of these regulatory requirements.

**DATES:** OMB has up to 60 days to approve or disapprove this information collection request but may respond after 30 days; therefore, you should submit your public comments to OMB by June 15, 2015 for the assurance of consideration.

**ADDRESSES:** You may submit your written comments directly to the Desk Officer for the Department of the Interior (OMB Control Number 1012—NEW), Office of Information and Regulatory Affairs, OMB, by email to *OIRA_Submission@omb.eop.*gov or telefax at (202) 395–5806. Please also mail a copy of your comments to Mr. Luis Aguilar, Regulatory Specialist,

ONRR, P.O. Box 25165, MS 61030A, Denver, Colorado 80225–0165, or email *Luis.Aguilar@onrr.gov.* Please reference OMB Control Number 1012—NEW in your comments.

**FOR FURTHER INFORMATION CONTACT:** For questions on technical issues, contact Jonathan Swedin, Program & Performance Analysis, ONRR, telephone (303) 231–3028, or email *jonathan.swedin@onrr.gov.* For other questions, contact Mr. Luis Aguilar, telephone (303) 231–3418, or email *luis.aguilar@onrr.gov.* You may also contact Mr. Aguilar to obtain copies (free of charge) of the ICR and any associated forms. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:**

## 1. Abstract

The Secretary of the U.S. Department of the Interior is responsible for mineral resource development on Federal and Indian lands and the Outer Continental Shelf (OCS). Under various laws, the Secretary's responsibility is to manage mineral resources production on Federal and Indian lands and the OCS, collect the royalties and other mineral revenues due, and distribute the funds collected under those laws. ONRR performs the royalty management functions and assists the Secretary in carrying out the Department's responsibility. We have posted those laws pertaining to mineral leases on Federal and Indian lands and the OCS at *http://www.onrr.gov/Laws_R_D/PubLaws/default.htm.*

In September 2011, President Obama announced the U.S. commitment to domestic implementation of EITI, a key element of the President's Open Government Partnership commitments. President Obama appointed the Secretary of the Interior as the senior U.S. official to lead the USEITI implementation. EITI is a voluntary global effort designed to strengthen transparency, accountability, and public trust for the revenues paid and received for a country's oil, gas, and mineral resources. The Administration renewed its commitment to implement EITI in the December 2013 U.S. Open Government National Action Plan. By signing onto the global EITI standard, the U.S. Government will help ensure that American taxpayers are receiving every dollar due for the extraction of these valuable public resources. The EITI Standard contains the set of requirements that countries need to meet in order to be recognized first as an EITI Candidate and ultimately as an EITI Compliant Country. In March 2014, the U.S. became the first G7 country to achieve Candidate Country status. When fully implemented, EITI will ensure more transparency in how the country's natural resources are governed and also will provide full disclosure of government revenues from its extractive sector.

The following laws and executive initiative are applicable to USEITI, including the Secretary's and ONRR's management of mineral resource production, revenue, and information disclosure obligations:

- U.S. Open Government National Action Plan
- Freedom of Information Act, as amended (5 U.S.C. 552)
- Outer Continental Shelf Lands Act, as amended (43 U.S.C. 1331–56b), including provisions of the Energy Policy Act of 2005 (42 U.S.C. 15801 *et seq.*)
- Federal Oil and Gas Royalty Management Act of 1982 as amended by the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (30 U.S.C. 1701–1759)
- Geothermal Steam Act of 1970 (30 U.S.C. 1001–28)
- Mineral Leasing Act (30 U.S.C 181–287)
- Mineral Leasing Act for Acquired Lands (30 U.S.C 351–60)

*General Information*

International EITI requirements direct participating governments to publish annual reports to help citizens understand how governments manage their extractive sectors. The U.S. Open Government National Action Plan commits the U.S. to publish the first United States EITI report in 2015 and to achieve EITI compliance in 2016. An Independent Administrator produces the annual reports, which include parallel public disclosures by both the government and companies. These disclosures relate to the payments that companies have made to the government on their oil, gas, and mining development.

In order to produce the USEITI annual reports, the Independent Administrator, in partnership with industry and DOI, created a document called the ''USEITI Reporting Form,'' including reporting instructions, which provide guidance on how to complete this form. The Independent Administrator will use this form to collect revenue information from extractive companies which paid more than $20 million to ONRR in a given year. The form will collect information on the amounts of royalties, rentals, and other payments related to mineral development that companies have made to the Federal Government. The Independent Administrator will collect this information; however, it will not collect items of a sensitive nature such as proprietary data, Personally Identifiable Information, etc. EITI is a voluntary initiative, and companies are not required to provide the requested information.

*OMB Approval*

We are requesting OMB's approval to collect this information. This ICR is necessary to successfully implement EITI in the U.S. Not collecting this information would limit the Secretary's ability to implement the U.S. Open Government National Action Plan and could prevent the Independent Administrator from creating and completing the annual USEITI report. If the annual USEITI report is not completed, the U.S. will not become an EITI Compliant Country.

## II. Data

*Title:* United States Extractive Industries Transparency Initiative (USEITI) Revenue Information Collection.

*OMB Control Number:* 1012—NEW.

*Bureau Form Number:* None.

*Frequency:* Annually.

*Estimated Number and Description of Respondents:* 76 extractive companies that paid $20 million or more to ONRR in calendar year 2013.

*Estimated Annual Reporting and Recordkeeping ''Hour'' Burden:* 6,384 hours. We estimate that each response will take approximately 84 hours for each company to complete. We have not included in our estimates certain requirements performed in the normal course of business and considered usual and customary.

*Estimated Annual Reporting and Recordkeeping ''Non-hour'' Cost Burden:* We have identified no ''non-hour'' cost burden associated with the collection of information.

*Public Disclosure Statement:* The PRA (44 U.S.C. 3501 *et seq.*) provides that 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.

## III. Request for Comments

Section 3506(c)(2)(A) of the PRA requires each agency to ''* * * publish a 60-day notice in the **Federal Register** * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *.'' Agencies must specifically solicit comments to: (a) Evaluate whether the

proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

To comply with the public consultation process, we published a notice in the **Federal Register** on December 18, 2014 (79 FR 75583) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. We received no comments in response to the notice.

If you wish to comment in response to this notice, you may send your comments to the offices listed under the **ADDRESSES** section of this notice. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, to ensure maximum consideration, OMB should receive public comments by June 15, 2015.

*Public Comment Policy:* ONRR will post all comments, including names and addresses of respondents at *http://www.regulations.gov.* Before including Personally Identifiable Information (PII), such as your address, phone number, email address, or other personal information in your comment(s), you should be aware that your entire comment (including PII) may be made available to the public at any time. While you may ask us to withhold PII from public view, we cannot guarantee that we will be able to do so.

Dated: May 12, 2015.

**Gregory J. Gould,**

*Director, Office of Natural Resources Revenue.*

[FR Doc. 2015–11799 Filed 5–14–15; 8:45 am]

**BILLING CODE 4335–30–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 701–TA–513 and 731–TA–1249 (Final)]**

## Sugar From Mexico; Revised Schedule for the Subject Investigations

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**DATES:** *Effective Date:* May 11, 2015.

**FOR FURTHER INFORMATION CONTACT:** Amy Sherman (202–205–3289), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:** On November 3, 2014, the Commission established a schedule for the conduct of the final phase of the subject investigations (79 FR 75591, December 18, 2014). On December 19, 2014, the Department of Commerce suspended the antidumping and countervailing duty investigations on sugar from Mexico (79 FR 78039, 78044, December 29, 2014). Subsequently, the Department of Commerce received timely requests to continue the antidumping and countervailing duty investigations on sugar from Mexico and resumed its investigations on May 4, 2015 (80 FR 25278, May 4, 2015). The Commission, therefore, is revising its schedule to conform with Commerce's new schedule.

The Commission's new schedule for the investigation is as follows. The prehearing staff report will be placed in the nonpublic record on August 28, 2015. The deadline for filing prehearing briefs is September 4, 2015. Requests to appear at the hearing must be filed with the Secretary to the Commission not later than September 11, 2015. The prehearing conference will be held at the U.S. International Trade Commission Building on September 14, 2015, if deemed necessary. The hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on September 16, 2015. The deadline for filing posthearing briefs is September 23, 2015. The Commission will make its final release of information on October 14, 2015; and final party comments are due on October 16, 2015.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: May 12, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015–11777 Filed 5–14–15; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

## Importer of Controlled Substances Registration: Cambrex Charles City

**ACTION:** Notice of registration.

**SUMMARY:** Cambrex Charles City applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cambrex Charles City registration as an importer of those controlled substances.

**SUPPLEMENTARY INFORMATION:** By notice dated January 21, 2015, and published in the **Federal Register** on January 28, 2015, 80 FR 4592, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616–3466 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice. Comments and request for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Cambrex Charles City to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the basic classes of controlled substances:

| Controlled substance | Schedule |
|---|---|
| 4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333). | II |
| Phenylacetone (8501) | II |
| Opium, raw (9600) | II |
| Poppy Straw Concentrate (9670) | II |

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers.

On September 29, 2014, Cambrex Charles City withdrew its request for the addition of Cocaine (9041), to this registration.

Dated: May 11, 2015.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator.*

[FR Doc. 2015–11768 Filed 5–14–15; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On May 7, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Idaho in the lawsuit entitled *United States and State of Idaho* v. *City of Jerome, Idaho,* Civil Action No. 15–155.

The Complaint alleges that the City of Jerome discharged pollutants from its publicly owned wastewater treatment facility and sanitary sewer collection system, in violation of its National Pollutant Discharge Elimination System permit, issued by EPA pursuant to the Clean Water Act. Under the proposed Consent Decree, the City commits to upgrading the capacity of its wastewater treatment facility and payment of $86,000 in penalty. Pursuant to Section 309(e) of the Clean Water Act, 33 U.S.C. 1319(e), the State of Idaho is named as a co-plaintiff.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Idaho* v. *City of Jerome, Idaho,* D.J. Ref. No. 90–5–1–1–10697. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| *To submit comments:* | *Send them to:* |
|---|---|
| By email | *pubcomment-ees.enrd@usdoj.gov.* |
| By mail | Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611. |

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11 (25 cents per page reproduction cost) payable to the United States Treasury.

**Susan M. Akers,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2015–11743 Filed 5–14–15; 8:45 am]

**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

**[OMB Number 1103–0093]**

### Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; COPS Extension Request Form

**AGENCY:** Community Oriented Policing Services (COPS) Office, Department of Justice.

**ACTION:** 60-Day notice.

**SUMMARY:** The Department of Justice (DOJ), Community Oriented Policing Services (COPS) Office, 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.

**DATES:** Comments are encouraged and will be accepted for 60 days until July 14, 2015.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kimberly J. Brummett, Program Specialist, Department of Justice, Community Oriented Policing Services (COPS) Office, 145 N Street NE., Washington, DC 20530 (202–353–9769).

**SUPPLEMENTARY INFORMATION:** 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 Bureau of Justice Statistics, 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;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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:* Revision of a currently approved collection, with change; comments requested.

2. *The Title of the Form/Collection:* COPS Extension Request Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice, Community Oriented Policing Services (COPS) Office.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Law enforcement agencies and other COPS grants recipients that have grants expiring within 90 days of the date of the form/request. The extension request form will allow recipients of COPS grants the opportunity to request a ''no-cost'' time extension in order to complete the federal funding period and requirements for their grant/cooperative agreement award. Requesting and/or receiving a time extension *will not* provide additional funding.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that approximately 2,700 respondents annually will complete the form within 30 minutes.

6. *An estimate of the total public burden (in hours) associated with the collection:* 1,350 total annual burden hours (0.5 hours × 2,700 respondents + 1,350 total burden hours).

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 12, 2015.

**Jerri Murray,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2015–11733 Filed 5–14–15; 8:45 am]

**BILLING CODE 4410–AT–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Decree Under the Clean Air Act, Clean Water Act, and Emergency Planning and Community Right To Know Act

On May 11, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of New York in the lawsuit entitled *United States and State of New York* v. *Tonawanda Coke Corporation,* Civil Action No. 1:15–cv–00420–WMS.

The Consent Decree resolves the claims of the United States and the State of New York set forth in the complaint against Tonawanda Coke Corporation for violations of the Clean Air Act, the Clean Water Act, and the Emergency Planning and Community Right to Know Act, in connection with its facility located in Tonawanda, New York. Under the Consent Decree, Tonawanda Coke Corporation has agreed to pay a civil penalty of $2,750,000. Of that penalty, $1,750,000 will be paid to the United States and $1,000,000 will be paid to the State of New York. Tonawanda Coke Corporation will also perform a wetlands preservation supplemental environmental project valued at $357,143 and fund a $1,000,000 state-led environmental benefit project fund. In addition, Tonawanda Coke Corporation will perform the injunctive relief required under the Consent Decree.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division and should refer to *United States and State of New York* v. *Tonawanda Coke Corporation,* D.J. Ref. No. 90–5–2–1–09994. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| *To submit comments:* | *Send them to:* |
|---|---|
| By email ..... | *pubcomment-ees.enrd@usdoj.gov.* |
| By mail ..... | Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611. |

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $29.50 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $20.50.

**Maureen Katz,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2015–11764 Filed 5–14–15; 8:45 am]

**BILLING CODE 4410–15–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 extension of the International Price Program U.S. Import and Export Price Indexes. 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 July 14, 2015.

**ADDRESSES:** Send comments to Nora Kincaid, 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:** Nora Kincaid, BLS Clearance Officer, 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

**SUPPLEMENTARY INFORMATION**

### I. Background

The U.S. Import and Export Price Indexes, produced by the Bureau of Labor Statistics' International Price Program (IPP), measure price change over time for all categories of imported and exported products, as well as selected services. The IPP has produced the U.S. Import Price Indexes continuously since 1973 and the U.S. Export Price Indexes continuously since 1971. The Office of Management and Budget has listed the Import and Export Price Indexes as a Principal Federal Economic Indicator since 1982. The indexes are widely used in both the public and private sectors. The primary public sector use is the deflation of the U.S. monthly Trade Statistics and the quarterly estimates of U.S. Gross Domestic Product; the indexes also are used in formulating U.S. trade policy and in trade negotiations with other countries. In the private sector, uses of the Import Price Indexes include market analysis, inflation forecasting, contract escalation, and replacement cost accounting.

The IPP indexes are closely followed statistics, and are viewed as a key indicator of the economic environment. The U.S. Department of Commerce uses the monthly statistics to produce monthly and quarterly estimates of inflation-adjusted trade flows. Without continuation of data collection, it would be extremely difficult to construct accurate estimates of the U.S. Gross Domestic Product. In fact, DOL–BLS'

attempt to curtail publication of the export price indexes beginning in FY15 was met with resistance from the Commerce Department who explained that a viable substitute is not available. The *Beyond the Numbers* article ''Analyzing alternatives to export price indexes'' (*http://www.bls.gov/opub/btn/volume-3/analyzing-alternatives-to-export-price-indexes.htm*) explores alternatives to using IPP's export price indexes to deflate the U.S. Gross Domestic Product and explains why there are currently no comparable replacements.

Additionally, Federal policymakers in the Department of Treasury, the Council of Economic Advisers, and the Federal Reserve Board utilize these statistics on a regular basis to improve these agencies' formulation and evaluation of monetary and fiscal policy and evaluation of the general business environment.

## II. Current Action

Office of Management and Budget clearance is being sought for the U.S. Import and Export Price Indexes. The IPP continues to modernize data collection and processing to permit more timely release of its indexes, and to reduce reporter burden. The IPP has expanded the use of its web application, introduced in 2003 to allow respondents to update their data online and more rapidly than using a paper-based form. Through March 2015, 89 percent of IPP respondents were providing prices via the web application or had agreed to start using this repricing method. Field Economists currently offer web repricing to all new respondents and at initiation, it is the preferred method of collection offered to companies. IPP continues to reduce burden for web respondents through system enhancements.

IPP has also facilitated the registration process for respondents who are currently using web repricing to provide prices for the Producer Price Index and who have also been initiated to provide prices (online) for IPP. The new process allows these multi-program respondents to self-register following the steps outlined in a pamphlet. Under the old process, IPP staff had to work with PPI staff on technical changes before multi-program respondents could set up and begin web repricing for IPP. Respondents therefore had to wait (multiple days) for an IPP staff member to contact them and walk them through the web repricing set-up.

The Program also continues its multi-year effort to develop a more effective sampling and collection strategy for companies that are considered major importers or exporters. Research has shown that, while hundreds of thousands of companies import and export goods into and from the United States each year, the volume of trade (in terms of dollar value) is heavily concentrated on a very small percentage of these companies. IPP is developing a plan for conducting a pilot for a limited set of major companies for the selected alternative resampling strategy. This approach would reduce burden by avoiding continual visits that are part of the current resampling strategy.

## 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.
- 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:* Extension without change of a currently approved collection.

*Agency:* Bureau of Labor Statistics.

*Title:* International Price Program (IPP) U.S. Import and Export Price Indexes.

*OMB Number:* 1220–0025.

*Affected Public:* Private Sector, Business or other for-profits.

ESTIMATED TOTAL BURDEN HOURS

| Form | Total respondents | Frequency | Total responses | Average time per response | Estimated total burden |
|---|---|---|---|---|---|
| Form 3008 | | Annually | | | |
| Imports | 1800 | | 1800 | 1.0 hour | 1800 hours. |
| Exports | 1200 | | 1200 | 1.0 hour | 1200 hours. |
| Total | 3000 | | 3000 | | 3,000 hours. |
| Form 3007D | | Monthly | | | |
| Imports | 3000 | 8.8[1] | 26400 | .4260[2] hours | 11246 hours. |
| Exports | 1950 | 9.0[1] | 17550 | .4022[3] hours | 7059 hours. |
| Total | 4950 | | 43950 | | 18305. |
| Totals | | | 46950 | | 21305. |

[1] During initiation, the respondent determines how many months he/she will need to supply data in a given year based upon how often the company changes its pricing information. The average company is requested to supply information 9.0 months per year for exports and 8.8 months per year for imports.

[2] Time to reprice is based upon 5 minutes of response time per item × 5.113 items = 25.565 minutes/60 =.4260 hours.

[3] Time to reprice is based upon 5 minutes of response time per item × 4.826 items = 24.130 minutes/60 = .4022 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 12th day of May 2015.

**Kimberly D. Hill,**

*Chief, Division of Management Systems, Bureau of Labor Statistics.*

[FR Doc. 2015–11737 Filed 5–14–15; 8:45 am]

**BILLING CODE 4510–24–P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

### Petitions for Modification of Application of Existing Mandatory Safety Standards

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations, 30 CFR part 44, govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

**DATES:** All comments on the petitions must be received by the Office of Standards, Regulations, and Variances on or before June 15, 2015.

**ADDRESSES:** You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, Attention: Sheila McConnell, Acting Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk on the 21st floor. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

**FOR FURTHER INFORMATION CONTACT:** Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

### II. Petitions for Modification

*Docket Number:* M–2015–011–C.

*Petitioner:* GCC Energy, LLC, 6473 County Road 120, Hesperus, Colorado 81326.

*Mine:* King II Mine, MSHA I.D. No. 05–04864, located in La Plata County, Colorado.

*Regulation Affected:* 30 CFR 77.1403 (Daily examination of hoisting equipment).

*Modification Request:* The petitioner requests a modification of the existing standard that requires examinations of hoists and elevators as it applies to a new limited use/limited application wheelchair lift elevator system. The petitioner states that:

1. This wheelchair lift will not carry miners into the mine on regularly scheduled shifts.

2. The wheelchair lift is located on the South end of our two-story bathhouse next to the stairs accessing the second floor where Engineering and Superintendent offices are located. GCC Energy LLC is in a new building located on the surface area of an underground mine site. A new two-stop limited use/limited application elevator system has been installed. The purpose and intent of the hoist is for handicap access to the offices on the second floor of the bathhouse.

3. The wheelchair lift is installed and designed to comply with the Americans with Disabilities Act.

4. Title 30 CFR 77.1403 requires daily examinations of hoists and elevators, and 30 CFR 77.1404 requires that the person making the examination certify that the examination has been made. The records are to be kept for one year.

5. The Colorado Department of Labor and Employment, Division of Oil and Public Safety (OPS), Conveyance Program protects the riding public and industry personnel in the State of Colorado from the hazards of dangerous conveyances. To achieve this mission, the OPS requires the following:

(a) That all elevators, escalators, dumbwaiters, wheelchair lifts, APM and other regulated conveyances located in Colorado be registered with OPS.

(b) The installation, alteration, maintenance, testing, and annual inspection of regulated conveyances be completed according to the Colorado conveyance regulations, industry code and standard adopted in statute and regulation.

(c) That all conveyance contractors, mechanics, and inspectors maintain a current license issued by OPS and that the installation, alteration, maintenance, and examinations of regulated conveyances are completed by licensed and qualified personnel.

6. The petitioner states that GCC Energy does not employ a licensed OPS inspector. Accordingly, GCC seeks relief from the requirements of daily examination and recordkeeping of hoisting equipment. GCC Energy changes light bulbs in the cabin and records the phase 1 fire tests done monthly in the cabin. The control panel or inspection covers are not opened by GCC, and GCC does not perform any service or maintenance on the lift. Every five years a witness test with a licensed mechanic must be performed.

7. The elevator is a wheelchair lift with a single hydraulic cylinder traveling approximately 12 feet, not to exceed 30 feet per minute, that is roped so as not to allow over-extension. The cabin is attached to the cylinder. There are no wire ropes, sheave wheels, sheaves, or thimbles that must be examined daily for wear, and no damaged or worn bearings or broken wires.

8. GCC Energy, LLC is petitioning to allow the licensed inspectors to do the examinations and the licensed mechanics to do all repairs.

The petitioner asserts that the proposed alternative method will

increase the safety of the miners and afford them no less than the same level of protection as the existing standard.

*Docket Number:* M–2015–012–C.

*Petitioner:* Peabody Midwest Mining, LLC, P.O. Box 369, Coulterville, Illinois.

*Mine:* Gateway North Mine, MSHA I.D. No. 11–03235, located in Randolph County, Illinois.

*Regulation Affected:* 30 CFR 75.1909(b)(6) (Nonpermissible diesel-powered equipment; design and performance requirements).

*Modification Request:* The petitioner requests a modification of the existing standard to permit the use of a Getman Road Builder as it was originally designed, without front brakes. The petitioner states that:

(1) The existing standard for self-propelled nonpermissible diesel-powered equipment does not address equipment with more than four wheels, specifically the Getman RDG–1504S Road Builder with six wheels. This machine has dual brake systems on the four rear wheels and it is designed to prevent a loss of braking due to a single component failure.

(2) The speed of the machine will be limited to 10 miles per hour by permanently blocking out any gear that would provide higher speed, or transmission and differential ratios that would limit the maximum speed to 10 miles per hour will be used.

(3) The grader operators will be trained to recognize appropriate speeds for different road conditions and slopes.

(4) The grader operators will be trained to lower the grader blade to provide additional stopping capability.

(5) The petitioner proposes to transfer the RDG–1540S Road Builder, serial number 6739, from the Gateway Mine that will be closing, to the New Gateway North Mine.

The petitioner asserts that if the machine is operated as described in the petition, the safety of the miners will not be compromised.

Dated: May 11, 2015.

**Sheila McConnell,**

*Acting Director, Office of Standards, Regulations, and Variances.*

[FR Doc. 2015–11713 Filed 5–14–15; 8:45 am]

**BILLING CODE 4510–43–P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice: 15–039]**

## Notice of Centennial Challenges 3D Printed Habitat Challenge—Design Competition

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of Centennial Challenges 3D Printed Habitat Challenge—Design Competition.

**SUMMARY:** This notice is issued in accordance with 51 U.S.C. 20144(c). The 3D Printed (3DP) Habitat Challenge—Design Competition is scheduled and teams that wish to compete may now register. Centennial Challenges is a program of prize competitions to stimulate innovation in technologies of interest and value to NASA and the nation. The 3DP Habitat Challenge is a prize competition designed to encourage development of new technologies, or application of existing technologies, in unique ways to advance additive construction systems and to advance multi-material usage. NASA is providing the prize purse.

**DATES:** The Design Competition registration opens May 16, 2015, and the competition will conclude on September 27, 2015.

**ADDRESSES:** The 3DP Habitat Challenge—Design Competition will initially be conducted virtually via electronic submissions. After a scored down select process, the remaining submissions will compete at the New York City Maker Faire.

**FOR FURTHER INFORMATION CONTACT:** To register for or get additional information regarding the 3D Printed Habitat Challenge—Design Competition, please visit: *http://AmericaMakes.us/Challenge.*

For general information on the NASA Centennial Challenges Program please visit: *http://www.nasa.gov/challenges.* General questions and comments regarding the program should be addressed to Sam Ortega, Centennial Challenges Program, NASA Marshall Space Flight Center Huntsville, AL 35812. Email address: *hq-stmd-centennialchallenges@mail.nasa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Summary

Competitors will design habitats making full (better) use of additive construction (manufacturing) processes and techniques. Designs will be rated on concept, innovation, documentation, habitability, constructability, functionality, energy efficiency, and public appeal. Prizes will be awarded for first, second, and third place based on subject matter expert scoring and public voting.

### I. Prize Amounts

The total 3DP Habitat Challenge Design Competition prize purse is $50,000 (fifty thousand U.S. dollars). First place will receive $25,000 (twenty-five thousand U.S. dollars). Second place will receive $15,000 (fifteen thousand U.S. dollars). Third place will receive $10,000 (ten thousand U.S. dollars). Entries must meet specific requirements detailed in the Rules to be eligible for prize awards.

### II. Eligibility

To be eligible to win a prize, competitors must;

(1) Register and comply with all requirements in the rules and competitor agreement;

(2) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(3) Not be a Federal entity or Federal employee acting within the scope of their employment.

### III. Rules

The complete rules for the 3DP Habitat Challenge—Design Competition can be found at: *http://AmericaMakes.us/Challenge.*

**Cheryl Parker,**

*NASA Federal Register Liaison Officer.*

[FR Doc. 2015–11727 Filed 5–14–15; 8:45 am]

**BILLING CODE 7510–13–P**

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice: (15–031)]**

## Notice of Information Collection

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of information collection.

**SUMMARY:** The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

**DATES:** All comments should be submitted within 60 calendar days from the date of this publication.

**ADDRESSES:** All comments should be addressed to Fran Teel, Mail Code JF000, National Aeronautics and Space Administration, Washington, DC 20546–0001 or *Frances.C.Teel@NASA.gov.*

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection

instrument(s) and instructions should be directed to Fran Teel, NASA PRA Clearance Officer, NASA Headquarters, 300 E Street SW., Mail Code JF000, Washington, DC 20546, or *Frances.C.Teel@NASA.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Abstract

NASA promotes activities to demonstrate innovative uses and practical benefits of NASA Earth science data, scientific knowledge, and technology. NASA's Applied Sciences Program established the DEVELOP National Program to research environmental management and public policy issues at the state and local level. Under the guidance of NASA and partner organization science advisors, DEVELOP enables participants to lead research projects that utilize NASA Earth observations to address community concerns and public policy issues. Through teams, DEVELOP participants gain experience by (1) utilizing NASA's Earth Science satellite and airborne resources, to include remote sensing and geographic information systems (GIS), and (2) communicating research results. DEVELOP projects serve the global community and extend NASA Earth Science research and technology to benefit society. A focus on both professional and personal development is central to DEVELOP's ten week sessions, which are conducted annually during the spring, summer, and fall.

The DEVELOP research opportunity is available to individuals 18 years and older and includes transitioning career professionals (including veterans of the Armed Forces), recent college/university graduates, and currently enrolled students. Information is collected through an online process from individuals interested in participating in the NASA DEVELOP Program for a ten week session. Information collected from individuals includes a completed application, academic transcript, resume, and two letters of recommendation references per applicant.

With the growing societal role of science and technology in today's global workplace, DEVELOP is fostering an adept corps of tomorrow's scientists and leaders.

## II. Method of Collection

Electronic.

## III. Data

*Title:* DEVELOP National Program Application.

*OMB Number:* 2700–XXXX.

*Type of review:* Existing collection in use without an OMB Control Number.

*Affected Public:* Individuals.

*Estimated Number of Respondents:* 2,850.

*Estimated Time per Response:* Variable.

*Estimated Total Annual Burden Hours:* 2,100.

*Estimated Total Annual Cost to Respondents:* $37,275.

## IV. Request for Comments

*Comments are invited on:* (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

**Fran Teel,**

*NASA PRA Clearance Officer.*

[FR Doc. 2015–11746 Filed 5–14–15; 8:45 am]

**BILLING CODE 7510–13–P**

---

# POSTAL REGULATORY COMMISSION

## Sunshine Act Meetings

**TIMES AND DATES:** June 1, 2015, at 11 a.m.; September 3, 2015, at 11 a.m.; December 3, 2015, at 11 a.m.

**PLACE:** Commission hearing room, 901 New York Avenue NW., Suite 200, Washington, DC 20268–0001.

**STATUS:** The Postal Regulatory Commission will hold public meetings to discuss the agenda items outlined below. Part of the meetings will be open to the public as well as audiocast, and the audiocast may be accessed via the Commission's Web site at *http://www.prc.gov.* Part of the meetings will be closed.

**MATTERS TO BE CONSIDERED:** The agenda for the Commission's June 1, 2015 meeting, September 3, 2015 meeting, and December 3, 3015 meeting include the items identified below.

**PORTIONS OPEN TO THE PUBLIC:**

1. Report from the Office of Public Affairs and Government Relations.
2. Report from the Office of General Counsel.
3. Report from the Office of Accountability and Compliance.

**PORTIONS CLOSED TO THE PUBLIC:**

4. Discussion of pending litigation.

**CONTACT PERSON FOR MORE INFORMATION:** David A. Trissell, General Counsel, Postal Regulatory Commission, 901 New York Avenue NW., Suite 200, Washington, DC 20268–0001, at 202–789–6820 (for agenda-related inquiries) and Shoshana M. Grove, Secretary of the Commission, at 202–789–6800 or *shoshana.grove@prc.gov* (for inquiries related to meeting location, changes in date or time of the meeting, access for handicapped or disabled persons, the audiocast, or similar matters). The Commission's Web site may also provide information on changes in the date or time of the meeting.

By direction of the Commission.

**Shoshana M. Grove,**

*Secretary.*

[FR Doc. 2015–11978 Filed 5–13–15; 4:15 pm]

**BILLING CODE 7710–FW–P**

---

# POSTAL REGULATORY COMMISSION

**[Docket Nos. MC2015–23 and CP2015–65; Order No. 2476]**

## Change in Postal Prices

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning a change in prices for Global Expedited Package Services Contracts Non-Published Rates 5. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* May 18, 2015.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6820.

**SUPPLEMENTARY INFORMATION:**

## Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

## I. Introduction

On May 7, 2015, the Postal Service filed notice of a change in prices not of general applicability for Global Expedited Package Services—Non-

Published Rates 5 (GEPS—NPR 5), resulting from its proposed creation of GEPS—NPR 5 Version 2 prices.[1] The Postal Service also asks that the Commission add GEPS—NPR 5 Version 2 to the GEPS—NPR 5 product grouping in the competitive product list within the Mail Classification Schedule. Notice at 9.

To support its Notice, the Postal Service filed a copy of the GEPS–NPR 5 Version 2 model contract; a copy of the Governors' Decision authorizing the product; a set of maximum and minimum prices; a certification of compliance with 39 U.S.C. 3633(a); a copy of a related management analysis; an application for non-public treatment; and supporting financial workpapers. The Postal Service also identified the Commission docket and the Governors' Decision associated with the price changes and addressed several differences between the GEPS—NPR 5 Version 2 model contract and the original GEPS—NPR 5 model contract. *Id.* at 5–7.

## II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–23 and CP2015–65 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filings are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than May 18, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis Kidd to serve as Public Representative in these dockets.

## III. Ordering Paragraphs

*It is ordered:*

1. The Commission establishes Docket Nos. MC2015–23 and CP2015–65 to consider the matters raised by the Notice.

2. Pursuant to 39 U.S.C. 505, Curtis Kidd is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than May 18, 2015.

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

By the Commission.

**Shoshana M. Grove,**

*Secretary.*

[FR Doc. 2015–11684 Filed 5–14–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of the United States Postal Service of Change in Prices for Global Expedited Package Services—Non-Published Rates 5 (GEPS—NPR 5 Version 2) and Application for Non-Public Treatment of Materials Files Under Seal, May 7, 2015 (Notice). The Notice was filed pursuant to 39 CFR 3015.5 and Order No. 2320. See Docket Nos. MC2015–23 and CP2015–29, Order No. 2320, Order Adding Global Expedited Package Services—Non-Published Rates Contract 5 (GEPS—NPR 5) to the Competitive Product List, January 13, 2015.

---

# RAILROAD RETIREMENT BOARD

## Privacy Act of 1974; New and Revised Systems of Records

**AGENCY:** Railroad Retirement Board.

**ACTION:** Notice: Publication of an updated routine use for RRB Privacy Act Systems of Records, RRB–21 and RRB–22.

**SUMMARY:** We are updating an existing routine use to release railroad worker identifying information to any last employer, or their designee allowing the RRB to verify entitlement for benefits.

**DATES:** These changes become effective as proposed without further notice on June 24, 2015. We will file a report of these Systems of Records Notices with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of Representatives; and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

**ADDRESSES:** Send comments to Ms. Martha P. Rico, Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

**FOR FURTHER INFORMATION CONTACT:** Mr. Timothy Grant, Chief Privacy Officer, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092; telephone 312–751–4869, or email at *tim.grant@rrb.gov.*

**SUPPLEMENTARY INFORMATION:** We are adding the term 'or their designee' to the existing routine uses for our Privacy Act System of Records Notices (SORNs), RRB–21(q) and RRB–22(d) respectively. This will allow the RRB to verify entitlement for benefits if the railroad worker's previous employer has designated a third party provider to manage their employment information.

By Authority of the Board.

**Martha P. Rico,**

*Secretary to the Board.*

* * * * *

### RRB–21

**SYSTEM NAME:**

Railroad Unemployment and Sickness Insurance Benefit System

**SYSTEM LOCATION:**

U.S. Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611. Regional and District Offices: See **Federal Register** notice 79 FR 58910, Appendix I, or our public Web site at: *http://www.rrb.gov/field/field.asp.*

**SECURITY CLASSIFICATION:**

None.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants and claimants for unemployment and sickness (including maternity) benefits under the Railroad Unemployment Insurance Act: Some railroad employees injured at work who did not apply for Railroad Unemployment Insurance Act benefits; all railroad employees paid separation allowances.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Information pertaining to payment or denial of an individual's claim for benefits under the Railroad Unemployment Insurance Act: Name, address, sex, social security number, date of birth, total months of railroad service (including creditable military service), total creditable compensation for base year, last employer and date last worked before applying for benefits, last rate of pay in base year, reason not working, applications and claims filed, benefit information for each claim filed, disqualification periods and reasons for disqualification, entitlement to benefits under other laws, benefit recovery information about personal injury claims and pay for time not worked, medical reports, placement data, correspondence and telephone inquiries to and about the claimant, record of protest or appeal by claimant of adverse determinations made on his claims.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 12(l) of the Railroad Unemployment Insurance Act (45 U.S.C. 351, *et. seq.*).

**PURPOSE(S):**

The purpose of this system of records is to carry out the function of collecting and storing information in order to administer the benefit program under the Railroad Unemployment Insurance Act.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:**

a. Beneficiary identifying information may be disclosed to third party contacts to determine if incapacity of the beneficiary or potential beneficiary to understand or use benefits exists, and to determine the suitability of a proposed representative payee.

b. In the event the Board has determined to designate a person to be the representative payee of an incompetent beneficiary, disclosure of information concerning the benefit amount and other similar information may be made to the representative payee from the record of the individual.

c. Beneficiary identifying information, address, check rate, date and number may be released to the Treasury Department to control for reclamation and return outstanding benefit payments, to issue benefit payments, respond to reports of non-delivery and to insure delivery of check to the correct address or account of the beneficiary or representative payee.

d. Beneficiary identifying information, address, payment rate, date and number, plus other necessary supporting evidence may be released to the U.S. Postal Service for investigation of alleged forgery or theft of railroad unemployment/sickness benefit payments.

e. A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, provided that disclosure would be clearly in the furtherance of the interest of the subject individual.

f. Under Section 2(f), the Railroad Retirement Board has the right to recover benefits paid to an employee who later receives remuneration for the same period, therefore, the Railroad Retirement Board may notify the person or company paying the remuneration of the Board's right to recovery and the amount of benefits to be refunded.

g. Under Section 12(o), the Railroad Retirement Board is entitled to reimbursement of sickness benefits paid on account of the infirmity for which damages are paid, consequently, the Railroad Retirement Board may send a notice of lien to the liable party, and, upon request by the liable party, advise the amount of benefits subject to reimbursement.

h. Beneficiary identifying information, rate and entitlement data may be released to the Social Security Administration to correlate actions with the administration of the Social Security Act.

i. The last addresses and employer information may be released to Department of Health and Human Services in conjunction with the Parent Locator Service.

j. Benefit rate, entitlement and periods paid may be disclosed to the Social Security Administration, Bureau of Supplemental Security Income to federal, state and local welfare or public aid agencies to assist them in processing applications for benefits under their respective programs.

k. Beneficiary identifying information, entitlement, rate and other pertinent data may be released to the Department of Labor in conjunction with payment of benefits under the Federal Coal Mine and Safety Act.

l. Records may be referred to the General Accountability Office for auditing purposes and for collection of debts arising from overpayments under the Railroad Unemployment Insurance Act.

m. If a request for information pertaining to an individual is made by an official of a labor organization, of which the individual is a member, information from the record of the individual concerning his benefit or anticipated benefit and concerning the method of calculating that benefit may be disclosed to the labor organization official.

n. Pursuant to a request from an employer covered by the Railroad Retirement Act or the Railroad Unemployment Insurance Act, or from an organization under contract to an employer or employers, information regarding the Board's payment of unemployment or sickness benefits, the methods by which such benefits are calculated, entitlement data and present address may be released to the requesting employer or the organization under contract to an employer or employers for the purposes of determining entitlement to and rates of private supplemental pension, sickness or unemployment benefits and to calculate estimated benefits due.

o. Records may be disclosed in a court proceeding relating to any claims for benefits by the beneficiary under the Railroad Unemployment Insurance Act and may be disclosed during the course of an administrative appeal to individuals who need the records to prosecute or decide the appeal or to individuals who are requested to provide information relative to an issue involved in the appeal.

p. Beneficiary identifying information, entitlement data, benefit rates and periods paid may be released to the Veterans Administration to verify continued entitlement to benefits.

q. (Updated) Identifying information such as full name, social security number, employee identification number, date last worked, occupation, and location last worked may be released to any last employer, *or their designee,* to verify entitlement for benefits under the Railroad Unemployment Insurance Act.

r. The amount of unemployment benefits paid, if 10 dollars or more in a calendar year, and claimant identifying information, may be furnished to the Internal Revenue Service for tax administration purposes.

s. The name and address of a claimant may be released to a Member of Congress when the Member requests it in order that he or she may communicate with the claimant about legislation which affects the railroad unemployment insurance system.

t. Beneficiary identifying and claim period information may be furnished to states for the purposes of their notifying the RRB whether claimants were paid state unemployment or sickness benefits and also whether wages were reported for them. For claimants that a state identifies as having received state unemployment or sickness benefits, RRB benefit information may be furnished the state for the purpose of recovery of the amount of the duplicate payments which is made.

u. The amount of each sickness benefit that is subject to a tier 1 railroad retirement tax and the amount of the tier 1 tax withheld may be disclosed to the claimant's last railroad employer to enable that employer to compute its tax liability under the Railroad Retirement Tax Act.

v. The amount of sickness benefits paid and claimant identifying information, except for sickness benefits paid for an on-the-job injury, may be furnished to the Internal Revenue Service for tax administration purposes.

w. Entitlement data and benefit rates may be released to any court, state agency, or interested party, or to the representative of such court, state agency, or interested party in connection with contemplated or actual legal or administrative proceedings concerning domestic relations and support matters.

x. Identifying information and information about a claim for benefits filed may be disclosed to an employee's

base-year railroad employer and the employee's most recent railroad employer, if different, in order to afford that employer or those employers the opportunity to submit information concerning the claim. In addition, after the claim has been paid, if the base-year railroad employer appeals the decision awarding benefits, all information regarding the claim may be disclosed to such base-year railroad employer that is necessary and appropriate for it to fully exercise its rights of appeal.

y. Non-medical information relating to the determination of sickness benefits may be disclosed to an insurance company administering a medical insurance program for railroad workers for purposes of determining entitlement to benefits under that program.

z. Scrambled Social Security Number and complete home address information of unemployment claimants may be furnished to the Bureau of Labor Statistics for use in its Local Area Unemployment Statistics (LAUS) program.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper, microforms, magnetic tape, magnetic disk.

**RETRIEVABILITY:**

Social Security number (claim number) and name.

**SAFEGUARDS:**

*Paper and Microforms:* Maintained in areas not accessible to the public in metal filing cabinents. Access is limited to authorized RRB employees. Offices are locked during non-business hours. Building has 24 hour on-site security officers, closed circuit television monitoring and intrusion detection systems.

*Magnetic tape and disks:* Computer and computer storage rooms are restricted to authorized personnel; on-line query safeguards include a lock/unlock password system, a terminal oriented transaction matrix, role based access controls and audit trail. For electronic records, system securities are established in accordance with National Institute of Standards and Technology (NIST) guidelines, including network monitoring, defenses in-depth, incident response and forensics. In addition to the on-line query safeguards, they include encryption of all data transmitted and exclusive use of leased telephone lines.

**RETENTION AND DISPOSAL:**

*Paper and microform:* Destroyed by shredding in accordance with NIST standards, no sooner than 7 years and no later than 10 years after the close of the benefit year.

*Magnetic tape:* Records are retained for 90 days and then written over following NIST guidelines. For disaster recovery purposes certain tapes are stored 12–18 months.

*Magnetic disk:* Continually updated and retained for at least 7 but not more than 10 years after the close of the benefit year. When magnetic disk or other electronic media is no longer required or servicable, it is sanitized in accordance with NIST guidelines.

**SYSTEM MANAGER(S) AND ADDRESS:**

Office of Programs—Director of Policy and Systems, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611–2092.

**NOTIFICATION PROCEDURE:**

Requests for information regarding an individual's record should be in writing, including the full name, social security number and railroad retirement claim number (if any) of the individual. Before information about any record will be released, the individual may be required to provide proof of identity, or authorization from the individual to permit release of information. Such requests should be sent to: Office of Programs—Director of Unemployment & Program Support Division, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

**RECORD ACCESS PROCEDURE:**

See Notification section above.

**CONTESTING RECORD PROCEDURE:**

See Notification section above.

**RECORD SOURCE CATEGORIES:**

Applicant, claimant or his or her representative, physicians, employers, labor organizations, federal, state, and local government agencies, all Railroad Retirement Board files, insurance companies, attorneys, Congressmen, liable parties (in personal injury cases), funeral homes and survivors (for payment of death benefits).

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

* * * * *

## RRB–22

**SYSTEM NAME:**

Railroad Retirement, Survivor, and Pensioner Benefit System.

**SYSTEM LOCATION:**

U.S. Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 Regional and District Offices: See **Federal Register** notice 79 FR 58910, Appendix I, or our public Web site at: *http://www.rrb.gov/field/field.asp.*

**SECURITY CLASSIFICATION:**

None.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

(Updated) Applicants for retirement and survivor benefits, (spouses, divorced spouses, widows, surviving divorced spouses, children, students, parents, grandchildren), and individuals who filed for lump-sum death benefits and/or residual payments.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Information pertaining to the payment or denial of an individual's claim for benefits under the Railroad Retirement Act: Name, address, social security number, claim number, proofs of age, marriage, relationship, death, military service, creditable earnings and service months (including military service), entitlement to benefits under the Social Security Act, programs administered by the Veterans Administration, or other benefit systems, rates, effective dates, medical reports, correspondence and telephone inquiries to and about the beneficiary, suspension and termination dates, health insurance effective date, option, premium rate and deduction, direct deposit data, employer pension information, citizenship status and legal residency status (for annuitants living outside the United States), and tax withholding information (instructions of annuitants regarding number of exemptions claimed and additional amounts to be withheld, as well as actual amounts withheld for tax purposes).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 7(b)(6) of the Railroad Retirement Act of 1974 (U.S.C. 231f(b)(6)).

**PURPOSE(S):**

Records in this system of records are maintained to administer the benefit provisions of the Railroad Retirement Act, sections of the Internal Revenue Code related to the taxation of railroad retirement benefits, and Title XVIII of the Social Security Act as it pertains to Medicare coverage for railroad retirement beneficiaries.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:**

a. Beneficiary identifying information may be disclosed to third party contacts

to determine if incapacity of the beneficiary or potential beneficiary to understand or use benefits exists, and to determine the suitability of a proposed representative payee.

b. In the event the Board has determined to designate a person to be the representative payee of an incompetent beneficiary, disclosure of information concerning the benefit amount and other similar information may be made to the representative payee from the record of the individual.

c. Entitlement and benefit rates may be released to primary beneficiaries regarding secondary beneficiaries (or vice versa) when the addition of such beneficiary affects either the entitlement or benefit payment.

d. (Updated) Identifying information such as full name, address, date of birth, social security number, employee identification number, and date last worked, may be released to any last employer, *or their designee,* to verify entitlement for benefits under the Railroad Retirement Act.

e. Beneficiary identifying information, address, check rates, number and date may be released to the Department of the Treasury to control for reclamation and return of outstanding benefit payments, to issue benefit payments, act on report of non-receipt, to insure delivery of payments to the correct address of the beneficiary or representative payee or to the proper financial organization, and to investigate alleged forgery, theft or unlawful negotiation of railroad retirement benefit checks or improper diversion of payments directed to a financial organization.

f. Beneficiary identifying information, address, check rate, date, number and other supporting evidence may be released to the U.S. Postal Service for investigation of alleged forgery or theft of railroad retirement or social security benefit checks.

g. Beneficiary identifying information, entitlement data, medical evidence and related evaluatory data and benefit rate may be released to the Social Security Administration and the Centers for Medicare & Medicaid Services to correlate actions with the administration of Title II and Title XVIII of the Social Security Act, as amended.

h. (Updated) Beneficiary identifying information, including social security account number, and supplemental annuity amounts may be released to the Internal Revenue Service.

i. Beneficiary identifying information, entitlement, benefit rates, medical evidence and related evaluatory data, and months paid may be furnished to the Veterans Administration for the purpose of assisting that agency in determining eligibility for benefits or verifying continued entitlement to and the correct amount of benefits payable under programs which it administers.

j. Beneficiary identifying information, entitlement data and benefit rates may be released to the Department of State and embassy and consular officials, the American Institute on Taiwan, and to the Veterans Administration Regional Office, Philippines, to aid in the development of applications, supporting evidence, and the continued eligibility of beneficiaries and potential beneficiaries living abroad.

k. Beneficiary identifying information, entitlement, benefit rates and months paid may be released to the Social Security Administration (Bureau of Supplemental Security Income) the Centers for Medicare & Medicaid Services, to federal, state and local welfare or public aid agencies to assist them in processing applications for benefits under their respective programs.

l. The last addresses and employer information may be released to the Department of Health and Human Services in conjunction with the Parent Locator Service.

m. Beneficiary identifying information, entitlement, rate and other pertinent data may be released to the Department of Labor in conjunction with payment of benefits under the Federal Coal Mine and Safety Act.

n. Medical evidence may be released to Board-appointed medical examiners to carry out their functions.

o. Information obtained in the administration of Title XVIII (Medicare) which may indicate unethical or unprofessional conduct of a physician or practitioner providing services to beneficiaries may be released to Professional Standards Review Organizations and State Licensing Boards.

p. Information necessary to study the relationship between benefits paid by the Railroad Retirement Board and civil service annuities may be released to the Office of Personnel Management.

q. Records may be disclosed to the General Accountability Office for auditing purposes and for collection of debts arising from overpayments under Title II and Title XVIII of the Social Security Act, as amended, or the Railroad Retirement Act.

r. Pursuant to a request from an employer covered by the Railroad Retirement Act or the Railroad Unemployment Insurance Act, or from an organization under contract to an employer or employers, information regarding the Board's payment of retirement benefits, the methods by which such benefits are calculated, entitlement data and present address may be released to the requesting employer or the organization under contract to an employer or employers for the purposes of determining entitlement to and rates of private supplemental pension, sickness or unemployment benefits and to calculate estimated benefits due.

s. If a request for information pertaining to an individual is made by an official of a labor organization of which the individual is a member and the request is made on behalf of the individual, information from the record of the individual concerning his benefit or anticipated benefit and concerning the method of calculating that benefit may be disclosed to the labor organization official.

t. Records may be disclosed in a court proceeding relating to any claims for benefits by the beneficiary under the Railroad Retirement Act, and may be disclosed during the course of an administrative appeal to individuals who need the records to prosecute or decide the appeal or to individuals who are requested to provide information relative to an issue involved in the appeal.

u. The amount of a residual lump-sum payment and the identity of the payee may be released to the Internal Revenue Service for tax audit purposes.

v. The amount of any death benefit or annuities accrued but unpaid at death and the identity of such payee may be released to the appropriate state taxing authorities for tax assessment and auditing purposes.

w. Beneficiary identifying information, including but not limited to name, address, social security account number, payroll number and occupation, the fact of entitlement and benefit rate may be released to the Pension Benefit Guaranty Corporation to enable that agency to determine and pay supplemental pensions to qualified railroad retirees.

x. Medical records may be disclosed to vocational consultants in administrative proceedings.

y. Date employee filed application for annuity to the last employer under the Railroad Retirement Act for use in determining entitlement to continued major medical benefits under insurance programs negotiated with labor organizations.

z. Information regarding the determination and recovery of an overpayment made to an individual may be released to any other individual from whom any portion of the overpayment is being recovered.

aa. The name and address of an annuitant may be released to a Member of Congress when the Member requests it in order that he or she may communicate with the annuitant about legislation which affects the railroad retirement system.

bb. Certain identifying information about annuitants, such as name, social security number, RRB claim number, and date of birth, as well as address, year and month last worked for a railroad, last railroad occupation, application filing date, annuity beginning date, identity of last railroad employer, total months of railroad service, sex, disability onset date, disability freeze onset date, and cause and effective date of annuity termination may be furnished to insurance companies for administering group life and medical insurance plans negotiated between certain participating railroad employers and railway labor organizations.

cc. For payments made after December 31, 1983, beneficiary identifying information, address, amounts of benefits paid and repaid, beneficiary withholding instructions, and amounts withheld by the RRB for tax purposes may be furnished to the Internal Revenue Service for tax administration purposes.

dd. Last address and beneficiary identifying information may be furnished to railroad employers for the purpose of mailing railroad passes to retired employees and their families.

ee. Entitlement data and benefits rates may be released to any court, state agency, or interested party, or to the representative of such court, state agency, or interested party, in connection with contemplated or actual legal or administrative proceedings concerning domestic relations and support matters.

ff. Identifying information about annuitants and applicants may be furnished to agencies and/or companies from which such annuitants and applicants are receiving or may receive worker's compensation, public pension, or public disability benefits in order to verify the amount by which Railroad Retirement Act benefits must be reduced, where applicable.

gg. Disability annuitant identifying information may be furnished to state employment agencies for the purpose of determining whether such annuitants were employed during times they receive disability benefits.

hh. Identifying information about Medicare-entitled beneficiaries who may be working may be disclosed to the Centers for Medicare & Medicaid Services for the purposes of determining whether Medicare should be the secondary payer of benefits for such individuals.

ii. Disclosure of information in claim folders is authorized for bonafide researchers doing epidemiological/mortality studies approved by the RRB who agree to record only information pertaining to deceased beneficiaries.

jj. Identifying information for beneficiaries, such as name, SSN, and date of birth, may be furnished to the Social Security Administration and to any State for the purpose of enabling the Social Security Administration or State through a computer or manual matching program to assist the RRB in identifying female beneficiaries who remarried but who may not have notified the RRB of their remarriage.

kk. An employee's date last worked, annuity filing date, annuity beginning date, and the month and year of death may be furnished to AMTRAK when such information is needed by AMTRAK to make a determination whether to award a travel pass to either the employee or the employee's widow.

ll. The employee's social security number may be disclosed to an individual eligible for railroad retirement benefits on the employee's earnings record when the employee's social security number would be contained in the railroad retirement claim number.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper, microforms, magnetic tape and magnetic disk.

**RETRIEVABILITY:**

Claim number, social security number and full name.

**SAFEGUARDS:**

*Paper and Microforms:* Maintained in areas not accessible to the public in metal filing cabinents. Access is limited to authorizied RRB employees. Offices are locked during non-business hours. Building has 24 hour on-site security officers, closed circuit television monitoring and intrusion detection systems.

*Magnetic tape and disks:* Computer and computer storage rooms are restricted to authorized personnel; on-line query safeguards include a lock/unlock password system, a terminal oriented transaction matrix, role based access controls and audit trail. For electronic records, system securities are established in accordance with National Institute of Standards and Technology (NIST) guidelines, including network monitoring, defenses in-depth, incident response and forensics. In addition to the on-line query safeguards, they include encryption of all data transmitted and exclusive use of leased telephone lines.

**RETENTION AND DISPOSAL:**

*Paper:* Identify and transfer inactive folders to FRC periodically, Transfer to National Archives 7 years after the close of the fiscal year folders were determined to be inactive.

*Electronically imaged documents:* Destroy 90 days after the date scanned into the system or after completion of the quality assurance process, whichever is later.

*Magnetic tape:* Magnetic tape records are used to daily update the disk file, are retained for 90 days and then written over. For disaster recovery purposes certain tapes are stored 12–18 months.

*Magnetic disk:* Continually updated and permanently retained.

Electronically imaged documents. Destroy/delete individual claimant data 7 years after the close of the fiscal year determined to be inactive.

**SYSTEM MANAGER(S) AND ADDRESS:**

Office of Programs—Director of Policy and Systems, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611–2092

**NOTIFICATION PROCEDURE:**

Requests for information regarding an individual's records should be in writing, including the full name, social security number and railroad retirement claim number(if any) of the individual. Before information about any records will be released, the individual may be required to provide proof of identity, or authorization from the individual to permit release of information. Such requests should be sent to: Director of Unemployment & Programs Support Division, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611–2092.

**RECORD ACCESS PROCEDURE:**

See Notification section above.

**CONTESTING RECORD PROCEDURE:**

See Notification section above.

**RECORD SOURCE CATEGORIES:**

Individual applicants or their representatives, railroad employers, other employers, physicians, labor organizations, federal, state and local government agencies, attorneys, funeral

homes, congressmen, schools, foreign government.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

* * * * *

Date: May 12, 2015.

**Martha P. Rico,**

*For The Board Secretary to the Board.*

[FR Doc. 2015–11745 Filed 5–14–15; 8:45 am]

**BILLING CODE 7905–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### Submission for OMB Review; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

*Extension:*

Rule 15g–5; SEC File No. 270–348, OMB Control No. 3235–0394.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15g–5—Disclosure of Compensation of Associated Persons in Connection with Penny Stock Transactions—(17 CFR 240.15g–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15g–5 requires brokers and dealers to disclose to customers the amount of compensation to be received by their sales agents in connection with penny stock transactions. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 221 broker-dealers will spend an average of 87 hours annually to comply with the rule. Thus, the total compliance burden is approximately 19,245 burden-hours per year.

Rule 15g–5 contains record retention requirements. Compliance with the rule is mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov*. Comments should be directed to: (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 by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or by sending an email to *PRA_Mailbox@sec.gov*. Comments must be submitted within 30 days of this notice.

Dated: May 11, 2015.

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11728 Filed 5–14–15; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–74923; File No. SR–CBOE–2015–030]**

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Floor Broker Errors and the Use of Floor Broker Error Accounts

May 11, 2015.

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 April 30, 2015, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to update its rules related to floor broker errors and the use of floor broker error accounts. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

**Chicago Board Options Exchange, Incorporated Rules**

* * * * *

**Rule 6.79. Floor Broker Practices**

*(a) Liquidation or Reduction of Error Account Positions. For a position obtained as a result of a bona fide error, a floor broker may reduce or liquidate a position in the floor broker's error account (''error account position'') in accordance with this Rule, but any profit/loss from the liquidation or reduction belongs to the floor broker (''liquidating floor broker'').*

*A liquidating floor broker may personally represent an order that will liquidate or reduce the broker's error account position (''liquidation order''); however, a liquidating floor broker may not cross a liquidation order with a client's order also represented by the liquidating floor broker, unless the liquidating floor broker either: (1) Prior to executing the orders, the liquidating floor broker informs the client of the broker's intention to execute the client's order against an order for the floor broker's error account and the client does not object; (2) the liquidating floor broker sends the liquidation order to an unassociated broker; or (3) the liquidating floor broker sends the client's order to a PAR Official. For 1 through 3 above, the client's order must either be displayed in the relevant order book or announced in open outcry in accordance with Rule 6.74. An unassociated broker for purposes of this rule is any broker who is not directly or indirectly controlling, controlled by, or under common control with the liquidating floor broker. After a floor broker executes a liquidation order, the floor brokers must notify the Exchange in a form and manner prescribed by the Exchange via Regulatory Circular.*

*(b) Erroneously Executed Orders. Orders erroneously executed (e.g., executing a call order as a put or a buy order as a sell) on the Exchange must clear in the error account of the floor broker that executed the erroneous order, unless the erroneously executed orders are nullified pursuant to a mutual agreement under Exchange Rules. It shall be considered conduct inconsistent with just and equitable principals of trade and a violation of Rule 4.1 for a floor broker to give a trade acquired through an error to another Trading Permit Holder or for a Trading*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

*Permit Holder to accept a transaction that another Trading Permit Holder acquired through an error. If a floor broker discovers an order was erroneously executed on the Exchange, the floor broker shall proceed as follows:*

*(i) If a better price is available at the time the error was discovered, the client's order is entitled to be executed at the better price. If a better price is not available, then the floor broker is responsible at the price at which the client's order should have been executed, and the floor broker shall either: (1) Execute the order at the available market and give the client a ''difference check'' or (2) execute the order out of the floor broker's error account and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. If executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).*

*(c) Lost or Misplaced Market Orders. If a floor broker fails to execute a market order, the client's order is entitled to an execution on up to the size of the disseminated bid or offer at the time the order was received or at a better price if it is available at the time the error is discovered. If a better price or the price the client's order is entitled to is not available at the time the error is discovered, the floor broker shall provide an execution in the manner described in (b)(i) above. If the unexecuted market order is in excess of the disseminated bid or offer at the time the order was received, the execution price on the additional contracts shall be negotiated between the floor broker and client.*

*(d) Legging Multi-Part Orders. A floor broker is not restricted from legging multi-part orders. For the purposes of this Rule, multi-part orders include complex orders, stock-option orders, and futures and option orders where one of the legs is executed on the Exchange. If a broker executes a leg of a complex option order, for example, the price of the remaining leg of the order must be within the current disseminated market (e.g., when a broker executes the buy side, the price of the sell side of the order must be at the disseminated offer price or lower). If a floor broker is unable to complete the execution of an order that the floor broker has legged, the floor broker must either: (1) Offer the executed leg to the client; (2) liquidate the leg and then offer the trade, regardless of whether it's a profit or loss, to the client; (3) execute the remaining leg(s) of the order at the available market and give the client a ''difference check''; or (4) execute the order out of the floor broker's error account and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. The floor broker must document the time and to whom the offer noted in (1) and (2) above was made and retain this record. If executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).*

(e) *Print-Throughs. A print-through on a limit order occurs when a trade is effected at a better price than the order's limit during the time that the order should have been represented in the crowd. The order that is 'printed-through' is entitled to the number of contracts which trade through the order's limit up to the number of contracts specified in the order. Generally, the order that is 'printed-through' should be given a better price if it is available at the time the error is discovered. However, under certain circumstances, such as a systems failure, where a large number of orders were not received or receipt was delayed, it would not be improper for a floor broker to execute the client's order at the original limit price rather than the better price. A floor broker shall generally proceed as follows when a print-through has occurred:*

*(i) If a floor broker discovers a print-through and a better price is available at that time, the client's order is entitled to be executed at the better price. If a better price is no longer available, then the floor broker is responsible at the original limit price and the floor broker shall either: (1) Execute the order at the available market and give the client a ''difference check'' or (2) execute the order out of the floor broker's error account and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. If executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).*

*(ii) If a print-through occurs on the opening, the order that is 'printed-through' is entitled to the number of contracts which print through at the opening price. If a better price than the opening price is available at the time the error is discovered, the client's order shall be filled at the better price; if a better price is not available, the floor broker shall either: (1) Execute the order at the available market and give the client a ''difference check'' or (2) execute the order out of the floor broker's error account and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. If executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).*

(f) *Stopping Orders. A floor broker may not ''Stop'' or guarantee an execution on a client's order the floor broker is holding from the floor broker's error account because doing so would be acting as a market-maker in violation of Rule 8.8.*

(g) *Documentation of Errors and Record Keeping Requirements. All transactions executed for a floor broker's error account must be documented. These records must be retained for a minimum of three years, the first two years in an easily accessible place.*

*Rules adopted by the SEC under the Securities Exchange Act of 1934 (the ''Act'') require that a floor broker keep a copy of every order the floor broker receives, including orders received via hand signals or phone, and all cancelled orders and unexecuted orders. A floor broker may arrange to have these records kept on the floor broker's behalf; however, it is still the responsibility of the floor broker to produce such documents upon request. These records must be retained for a minimum of three years, the first two years in an easily accessible place. Failure to do so is a violation of the Act, SEC Rules 17a–3 and 17a–4, and CBOE Rules 4.2 (''Adherence to Law'') and 15.1 (''Maintenance, Retention and Furnishing of Books, Records and Other Information'').*

. . .Interpretations and Policies:

*.01 A liquidating floor broker executing a liquidation order in accordance with this rule in the trading crowd where the broker is active as a floor broker is not a violation of Rule 8.8. Additionally, CBOE Rules generally do not prohibit a floor broker from entering into transactions on other exchanges for the floor broker's personal*

*account in financial instruments underlying or related to the classes in the trading crowd where the floor broker acts as a floor broker.*

*.02 Pursuant to the due diligence provisions of Rule 6.73, a floor broker's agency business has priority over the broker's liquidation orders.*

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is proposing to adopt new Rule 6.79 to codify policies related to floor broker errors and the use of floor broker error accounts. The proposed rule incorporates several aspects of CBOE Regulatory Circular RG95–49.[5] In addition, the proposed rule will supersede RG95–49. The Exchange believes it would be beneficial to codify policies related to floor broker errors and the use of floor broker error accounts in Exchange rules in order to provide further detail regarding errors and the use of error accounts.

First, with proposed Rule 6.79(a), the Exchange proposes to clarify and amend its policy related to a floor broker representing orders for the floor broker's own error account. The general principle is that for a position obtained as a result of a bona fide error, a broker may reduce or liquidate a position in the floor broker's error account (''error account position'') in accordance with proposed Rule 6.79, but any profit/loss from the liquidation or reduction belongs to the floor broker (''liquidating floor broker''). Furthermore, a liquidating floor broker may personally represent an order that will liquidate or reduce the floor broker's error account position (''liquidation order''). As stated, the proposed rule does not prohibit floor brokers from personally representing a liquidation order, except in limited circumstances. For example, a liquidating floor broker may not cross a liquidation order with a client's order[6] also represented by the floor broker, unless either: (1) Prior to executing the orders, the liquidating floor broker informs the client of the floor broker's intention to execute the client's order against an order for the floor broker's error account and the client does not object[7]; (2) the liquidating floor broker sends the liquidation order to an unassociated broker;[8] or (3) the liquidating floor broker sends the client's order to a PAR Official.[9] For 1 through 3 above, the client's order must either be displayed in the relevant order book or announced in open outcry in accordance with Rule 6.74.[10] An unassociated broker for purposes of this rule is any broker who is not directly or indirectly controlling, controlled by, or under common control with the liquidating broker. In addition, after a floor broker executes a liquidation order, the floor brokers must notify the Exchange in a form and manner prescribed by the Exchange via regulatory circular.[11] The Exchange believes the proposed method for liquidating an error account position is non-controversial because the procedural requirements, especially requiring the client's order to either be displayed in the relevant order book or announced in open outcry in accordance with Rule 6.74, help to ensure the client's order receives the best possible execution price.

Next, proposed Rule 6.79(b) requires erroneously executed orders (*e.g.,* executing a call order as a put or a buy order as a sell) to be cleared in the error account of the floor broker that executed the erroneous order (creating an ''error account position'') unless the erroneously executed orders are nullified pursuant to a mutual agreement under Exchange rules.[12] Furthermore, it will be considered a violation of just and equitable principles of trade and a violation of CBOE Rule 4.1 for a floor broker to give a trade acquired through error to another Trading Permit Holder (''TPHs'').[13] The proposed rule also makes it a violation of Rule 4.1 for a TPH to accept a trade that another TPH has acquired through an error. The Exchange believes that maintaining a uniform process for the handling of errors by floor brokers is appropriate. More specifically, by not allowing the transfer of error positions between floor brokers and market-makers, the Exchange is eliminating

[5] RG95–49 reissued Regulatory Circular RG94–44. RG94–44 was filed with the SEC and approved on June 1, 2014 [sic]. *See* SR–CBOE–93–44; Securities Exchange Act Release No. 34–34138 (June 7, 1994), 59 FR 108. The proposed rule will supersede RG95–49 and RG94–44.

[6] RG95–49 utilized the term customer. The proposed rule replaces 'customer' with 'client' in order to avoid confusion as to the type of 'customer' (*i.e.,* retail customer, client customer, etc.) referred to in RG95–49.

[7] In order to exit an error account position, floor brokers often solicit contra side orders. The Exchange believes floor brokers should be able to cross liquidating orders with those solicited orders. In addition, the Exchange notes that client consent is presumed only after the client has been properly notified. The Exchange also notes that the client may always object to the transaction, which will prohibit the floor broker from crossing the liquidation order with the objecting client's order. Additionally, notification will be made on a per order basis.

[8] The Exchange notes that sending the liquidation order to an unassociated broker removes the potential conflict of interest between a floor broker's due diligence requirements and the floor broker's personal interest in executing a trade for himself. In addition, as noted below, the client's order is further protected by requiring the order to either be displayed in the order book or announced via open outcry.

[9] RG95–49 utilized the term OBO's and DPM. The Exchange proposes to remove the reference to OBOs, as the Exchange no longer has OBOs. The Exchange also proposes to replace DPM with PAR Official.

[10] The Exchange believes client consent protects clients by allowing them to determine on a per order basis whether their interests are being served by trading with a liquidating floor broker. The Exchange also notes that the requirement to either display the client's order in the relevant order book or announce the crossing transaction in open outcry also serves to protect the client by ensuring the client's order has access to greater liquidity and potentially better prices.

[11] The Exchange notes that this provision will allow CBOE to surveil for potential abuses related to floor brokers liquidating positions, especially when a liquidating floor broker trades with a client order.

[12] CBOE Rule 6.19 currently provides that ''[a] trade on the Exchange may be nullified or adjusted if the parties to the trade agree to the nullification or adjustment.'' However, as part of an industry-wide initiative to harmonize exchange rules regarding obvious errors, Rule 6.19 will be replaced by revised Rule 6.25. With regards to mutually agreed nullifications and adjustments, revised Rule 6.25 is proposed to state that ''[a] trade may be nullified or adjusted on the terms that all parties to a particular transaction agree, provided, however, that such agreement to nullify or adjust must be conveyed to the Exchange in a manner prescribed by the Exchange prior to 7:30 a.m. Central Time on the first trading day following the execution. It is considered conduct inconsistent with just and equitable principles of trade for any TPH to use the mutual adjustment process to circumvent any applicable Exchange rule, the Act or any of the rules and regulations thereunder.'' *See* Securities Exchange Act Release No. 34–73884 (December 18, 2014), 79 FR 77557 (June 2, 2009 [sic]) (SR–BATS–2014–067).

[13] RG95–49 referred to Trading Permit Holders as ''members'', and the proposed rule seeks to update the terminology in this respect.

perceived conflicts of interest that may result from error account position transfers between TPHs.

In addition to the above restriction, proposed Rule 6.79(b)(i) provides that if a floor broker discovers an order was erroneously executed on the Exchange, the floor broker shall generally proceed as follows: If a better price is available at the time the error was discovered, the client's order is entitled to be executed at the better price. If a better price is not available, then the floor broker is responsible at the price at which the client's order should have been executed, and the floor broker shall either: (1) Execute the order at the available market and give the client a ''difference check'' or (2) execute the order out of the floor broker's error account [14] and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. Additionally, if executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a). The Exchange believes giving floor brokers the option to execute the client's order out of the floor broker's error account is non-controversial because RG95–49 generally provides the same relief for print-throughs, lost or misplaced market orders, and erroneously executed orders. Although under RG95–49 when a print-through, lost or misplaced market order, or erroneously executed order is discovered during trading hours floor brokers are prohibited from correcting the error by filling the client out of an error account if doing so would reduce or liquidate a position in the floor broker's error account, the proposed rule is non-controversial because the floor broker must follow the procedures outlined in paragraph (a) of Rule 6.79 whenever reducing or liquidating a position in the floor broker's error account. As noted above the procedural requirements of Rule 6.79(a), especially requiring the client's order to either be displayed in the relevant order book or announced in open outcry in accordance with Rule 6.74, help to ensure the client's order receives the best possible execution price.[15]

Next, proposed Rule 6.79(c) seeks to codify policies related to lost or misplaced market orders.[16] The Exchange believes it's beneficial to codify the lost or misplaced market orders policy because doing so more adequately notifies floor brokers of their obligations and clients of their rights regarding lost or misplaced market orders. The proposed rule mandates that if a floor broker fails to execute a market order that has been lost or misplaced, the client's order is entitled to an execution on up to the size of the disseminated bid or offer at the time the order was received or at a better price if it is available at the time the error is discovered. If a better price or the price the client's order is entitled to is not available at the time the error is discovered, the floor broker shall provide an execution in the manner described in (b)(i). If the unexecuted market order is in excess of the disseminated bid or offer at the time the order was received, the execution price on the additional contracts shall be negotiated between the floor broker and client.

Next, proposed Rule 6.79(d) sets forth specific policies related to legging multi-part orders.[17] The Exchange believes it's beneficial to describe the procedures a floor broker must follow when the broker is unable to complete an order the floor broker has legged. If a floor broker executes a leg of a complex option order, for example, the price of the remaining leg of the order must be within the current disseminated market (*e.g.,* when a broker executes the buy side, the price of the sell side of the order must be at the disseminated offer price or lower). If a floor broker is unable to complete the execution of an order that the floor broker has legged, the floor broker must either: (1) Offer the executed leg to the client; (2) liquidate the leg and then offer the trade, regardless of whether it's a profit or loss, to the client; (3) execute the remaining leg(s) of the order at the available market and give the client a difference check; or (4) execute the order out of the floor broker's error account [18] and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary. The floor broker must document the time and to whom the offer noted in (1) and (2) above was made and retain this record. Additionally, if executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).

Next proposed Rule 6.79(e) seeks to codify policies related to print-throughs.[19] The rule mandates that if a print-through is discovered the order that is 'printed-through' should be executed at the available market at the time the print-through is discovered. If the available market is at a better price, the order that is 'printed-through' is entitled to the better price. If the available market is at a worse price, the floor broker becomes responsible at the original limit price [20] and must either: (1) Execute the order at the available market while providing the client a ''difference check'' or (2) execute the order out of the floor broker's error account and notify a CBOE Official, in a form and manner prescribed by the Exchange and announced via Regulatory Circular, for potential reporting of the error account transaction as late or out of sequence as necessary.[21]

[14] The Exchange notes that the Continuous Trade Match System (''CTM'') is the mechanism by which a floor broker would execute a client's order out of the floor broker's error account.

[15] The Exchange believes that all similar provisions in this proposed rule that allow a floor broker to provide a fill out of the broker's error account are non-controversial for the same reasons outlined above.

[16] The Exchange notes, however, that this provision does not mandate that off floor brokers follow the procedures in 6.79(c); however, to the extent that a transaction is executed on the Exchange to fix an error due to a lost or misplaced market order, the broker will be held to the standard set forth in Rule 6.79(c).

[17] Multi-part orders include complex orders, stock-option orders, and futures and option orders where one of the legs is executed on the Exchange.

[18] The Exchange recognizes that RG95–49 stated that if a floor broker was unable to complete an order the broker legged, the broker could not provide an execution on the unexecuted portion of the order from the broker's error account because doing so would be acting as a market-maker in violation of Rule 8.8. The Exchange now believes that failing to complete an order that the broker has legged is as much an error as a print-through and providing an execution with an error account would not implicate Rule 8.8 in most situations. The Exchange recognizes, however, that a pattern and practice of consistently using the error account in this manner may lead the Exchange to the conclusion that a broker is acting like a market-maker in violation of Rule 8.8. The same is true for the other provisions of the proposed rule that allow a broker to provide a client a fill via the broker's error account.

[19] A print-through on a limit order occurs when a trade is effected at a better price than the order's limit during the time that the order should have been represented in the crowd. For example, a floor broker holds a client's limit order to sell at $1.00. If a trade occurs at $1.05 during the time in which the order should have been represented in the trading crowd, a print-through has occurred.

[20] The rule contemplates situations in which the client would not be entitled to the better price. For example, a systems failure that causes a large number of orders to not be received or if receipt was delayed.

[21] RG95–49 provided for three separate procedures for print-throughs (print throughs during trading hours; print-throughs outside trading hours; and print-throughs on the opening). Although the proposed rule includes a separate procedure for print-throughs occurring on the opening, the Exchange believes the proposed rule protects investors and avoids potential confusion

Additionally, if executing an order out of the floor broker's error account will reduce or liquidate a position in the floor broker's error account, the floor broker must follow the procedures in paragraph (a).

Next, proposed Rule 6.79(f) seeks to codify its policy related to stopping orders. Again, pursuant to Rule 8.8, the Exchange believes it is a violation of Rule 8.8 for a broker to ''Stop'' or guarantee an execution on a client's order he is holding from the floor broker's error account. The Exchange believes that prohibiting floor brokers from stopping orders or guaranteeing an execution on a client's order from the floor broker's error account ensures that the floor broker is acting in the best interest of the floor broker's client; rather than the interest of the broker's proprietary position.

Next, proposed Rule 6.79(g) seeks to codify its policy related to the documentation of errors and record keeping requirements. The proposed rule mandates that ''[a]ll transactions executed for a floor broker's error account must be documented.'' In addition, the ''records must be retained for a minimum of three years, the first two years in an easily accessible place.'' In addition, in order to further stress the importance of maintaining adequate and complete records, the Exchange specifies some of the records that must be maintained in accordance with the Securities Exchange Act of 1934, SEC Rules 17a–3 and 17a–4, and CBOE Rules 4.2 (''Adherence to Law'') and 15.1 (''Maintenance, Retention and Furnishing of Books, Records and Other Information), including all cancelled orders and unexecuted orders.

Next, the Exchange proposes to adopt Interpretation and Policy .01 to provide clarity regarding its policy prohibiting floor brokers from acting as market-makers. According to CBOE rules [22] floor brokers are generally prohibited from acting as a market-maker on the same business day in which they act as a floor broker. However, Rule 8.8 is not clear on whether a floor broker representing the broker's error account is acting as a market-maker. The Exchange does not believe in the ordinary course of business that a floor broker is acting as a market-maker when providing fills via an error account in accordance with this proposed rule or executing liquidating orders in accordance with this proposed rule. However, as noted previously, the Exchange recognizes that a pattern of consistently using an error account to provide fills to customers may lead the Exchange to the conclusion that a floor broker is acting as a market-maker in violation of Rule 8.8. In addition, although the proposed rule clearly states that a broker may execute liquidation orders, Interpretation and Policy .01 makes it abundantly clear that the prohibition against a broker acting as a market-maker does not apply to a liquidation order being executed by a liquidating floor broker in the trading crowd in which the floor broker is active. In addition, CBOE Rules generally do not prohibit a floor broker ''from entering into transactions on other exchanges for the floor broker's personal account in financial instruments underling or related [23] to the classes in the trading crowd where the floor broker acts as a floor broker.'' The Exchange notes, however, that it would be a violation of CBOE Rules 4.1 (''Just and Equitable Principles of Trade'') and 6.73 (''Responsibilities of Floor Brokers'') and Regulatory Circular RG94–76 (''Front-running of Blocks'') for a floor broker to enter into transactions in an underlying or related financial instrument based on information concerning a client's option order the floor broker holds, and regulatory staff monitors for such activity in the same manner it monitors for front-running generally. In addition, floor broker transactions in underlying or related financial instruments are not entitled to good faith credit under Regulation T and must be margined as customer transactions.

Finally, the Exchange proposes to adopt Interpretation and Policy .02 to make it clear that a broker's agency business takes priority over a floor broker's liquidation orders. For example, marketable agency orders should be executed prior to a broker attempting to liquidate or reduce the broker's error account position.

To conclude, the Exchange believes that the proposed rule is in furtherance of the Act because it will allow floor broker's a straight-forward mechanism for liquidating error account positions while protecting investors. As stated above, the Exchange intends to release a Regulatory Circular to announce the implementation of the Rule and other specifics surrounding the procedures of the implementation. In addition, prior to implementation, the Exchange will ensure it has proper policies and procedures in place to correctly administer the Rule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[24] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [25] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [26] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, in addition to codifying relevant portions of RG95–49, the Exchange believes that the proposed rule change enhances several aspects of RG95–49, which helps perfect the mechanism of a free and open market and protect investors and the public interest. Where RG95–49 disallows a floor broker from crossing a client order with an order for the broker's error account (*i.e.,* a client order reducing an error account position), the proposed rule allows the activity if certain procedures are followed (*e.g.,* notifying a client that the broker intends to execute the client's order against an order for the broker's error account in order to allow the client to consent to trade with the floor broker's error account), which promotes a free and open market by allowing brokers to source liquidity.

In addition, where RG95–49 ensured that a customer is entitled to only ten contracts at the disseminated bid or offer when a broker loses or misplaces

related to separate procedures by consolidating procedures related to print-throughs during trading hours and print-throughs outside trading hours. In addition, the Exchange notes that the proposed rule provides that for a print-through that occurs on the opening, the order that is 'printed-through' is entitled to the number of contracts which print through at the opening price. For print-throughs not occurring on the opening, the proposed rule does not limit the number of contracts to which the order is entitled.

[22] CBOE Rule 8.8.

[23] A related financial instrument would include index futures if you are an OEX or SPX floor broker, OEX options if you are an SPX floor broker, and SPX options if you are an OEX floor broker.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] *Id.*

a market order, the proposed rule provides that the customer is entitled to the price and size of the disseminated bid or offer, which the Exchange believes promotes just and equitable principles of trade because it more adequately reflects the size and price that a customer would have been entitled to if no mistake was made. Also, where RG95–49 prohibits the use of a floor broker error account to provide an execution to a client in certain circumstances (*e.g.,* when providing a fill from an error account to correct a print-through, lost or misplaced market order, or erroneously executed order would reduce or liquidate a position in the floor broker's error account or when providing a fill from an error account to provide an execution on an unexecuted portion of a multi-leg order,), the proposed rule gives the broker the flexibility to execute the order out of the broker's error account, which protects investors and the public interest by ensuring that customer orders are executed. As noted above, the Exchange believes giving floor brokers the option to correct an error by executing the client's order out of the floor broker's error account is non-controversial because RG95–49 generally provides the same relief for print-throughs, lost or misplaced market orders, and erroneously executed orders. Although under RG95–49 when a print-through, lost or misplaced market order, or erroneously executed order is discovered during trading hours floor brokers are prohibited from correcting the error by filling the client out of an error account if doing so would reduce or liquidate a position in the floor broker's error account, the proposed rule is non-controversial because the floor broker must follow the procedures outlined in paragraph (a) of Rule 6.79 whenever reducing or liquidating a position in the floor broker's error account. As noted above the procedural requirements of Rule 6.79(a), especially requiring the client's order to either be displayed in the relevant order book or announced in open outcry in accordance with Rule 6.74, help to ensure the client's order receives the best possible execution price. Finally, where RG95–49 provided for three separate procedures for print-throughs (print throughs during trading hours; print-throughs outside trading hours; and print-throughs on the opening), the proposed rule protects investors and avoids potential confusion related to separate procedures (even though the proposed rule maintains a separate procedure for print-throughs that occur on the opening) by consolidating procedures related to print-throughs during trading hours and print-throughs outside trading hours.

Additionally, the proposed rule prevents fraudulent and manipulative acts and practices by requiring brokers to clear errors in their own accounts unless nullified pursuant to a mutually agreement under Exchange rules. Furthermore, requiring floor brokers to notify the Exchange after executing an order for the floor broker's error account or providing a fill to a client via the floor broker's error account will aid the Exchange in the surveillance of error account activity, which helps prevent fraudulent and manipulative acts and practices and promotes just and equitable principles of trade. Finally, the Exchange believes the proposed rule promotes just and equitable principles of trade by ensuring client orders are not harmed for mistakes that are the fault of brokers. The Exchange does not believe the proposed rule is unfairly discriminatory toward customers, issuers, or brokers because the proposed rule simply sets forth the process for floor brokers to correct certain mistakes.

Finally, the proposed rule change is also consistent with Section 11(a)(1) of the Act and the rules promulgated thereunder. Generally, Section 11(a)(1) of the Act restricts any member of a national securities exchange from effecting any transaction on such exchange for (i) the member's own account, (ii) the account of a person associated with the member, or (iii) an account over which the member or a person associated with the member exercises discretion, unless a specific exemption is available. Examples of common exemptions include the exemption for transactions by broker dealers acting in the capacity of a market maker under Section 11(a)(1)(A), the ''G'' exemption for yielding priority to non-members under Section 11(a)(1)(G) of the Act and Rule 11a1–1(T) thereunder, and ''Effect vs. Execute'' exemption under Rule 11a2–2(T) under the Act. In this regard, we note that, consistent with existing Exchange Rules for effecting proprietary orders from on the floor of the Exchange, Floor Broker TPHs effecting orders for their error accounts and relying on the G exemption would be required to yield priority to any interest in the electronic book at the same price (not just public customer orders) to ensure that non-member interest is protected.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. More specifically, the Exchange does not believe the proposed rule changes will impose any burden on intramarket competition because it will be applicable to all floor brokers. In addition, the Exchange does not believe the proposed changes will impose any burden on intermarket competition because proposed Rule 6.79 simply provides a clearer mechanism for correcting errors.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [27] and Rule 19b-4(f)(6) [28] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.[29]

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

[27] 15 U.S.C. 78s(b)(3)(A).

[28] 17 CFR 240.19b–4(f)(6).

[29] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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 email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2015–030 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2015–030. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2015–030, and should be submitted on or before June 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11716 Filed 5–14–15; 8:45 am]

**BILLING CODE 8011–01–P**

[30] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. IC–31598; File No. 812–14368]**

## Business Development Corporation of America, et al.; Notice of Application

May 11, 2015.

**AGENCY:** Securities and Exchange Commission (''Commission'').

**ACTION:** Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

**SUMMARY OF APPLICATION:** Applicants request an order to permit business development companies (''BDCs'') to co-invest in portfolio companies with each other and with affiliated investment funds.

**APPLICANTS:** Business Development Corporation of America (''BDCA''); Business Development Corporation of America II (''BDCA II''); BDCA Venture, Inc. (''BDCA Venture,'' and BDCA Venture together with BDCA and BDCA II, the ''BDCA Funds''), BDCA Adviser, LLC (''BDCA Adviser''), on behalf of itself and its successors; [1] BDCA Adviser II, LLC (''BDCA Adviser II''), on behalf of itself and its successors; BDCA Venture Adviser, LLC, on behalf of itself and its successors (''BDCA Venture Adviser''); and BDCA Funding I, LLC; BDCA 2L Funding I, LLC; BDCA–CB Funding, LLC; and 54th Street Equity Holdings, Inc. (collectively, the ''Existing BDCA Subs'').

**DATES:** *Filing Dates:* The application was filed on October 2, 2014 and amended on March 13, 2015.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 8, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F St. NE., Washington, DC 20549–1090. Applicants: James A. Tanaka, General Counsel, RCS Capital, 405 Park Avenue, 14th Floor, New York, NY, 10022.

**FOR FURTHER INFORMATION CONTACT:** Michael S. Didiuk, Senior Counsel, at (202) 551–6839 or Holly Hunter-Ceci, Branch Chief, at (202) 551–6869 (Chief Counsel's Office, Division of Investment Management).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

### Applicants' Representations

1. BDCA, BDCA II and BDCA Venture are Maryland corporations organized as closed-end management investment companies that have elected to be regulated as BDCs under Section 54(a) of the Act.[2] BDCA's Objectives and Strategies [3] are to generate both current income and to a lesser extent long-term capital appreciation through debt and equity investments. BDCA invests primarily in first and second lien senior loans and mezzanine debt issued by middle market companies. BDCA II's Objectives and Strategies are to generate both current income and, to a lesser extent, capital appreciation through its investments. BDCA II intends to achieve this objective by investing in a portfolio composed primarily of leveraged loans. BDCA Venture's Objectives and Strategies are to maximize total return by generating current income from debt investments and, to a lesser extent, capital appreciation from equity and equity-related investments. BDCA Venture seeks to accomplish its total return objective by primarily lending with warrants to emerging growth

[1] The term ''successor,'' as applied to each Adviser, means an entity that results from a reorganization into another jurisdiction or change in the type of business organization.

[2] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[3] ''Objectives and Strategies'' means a Regulated Fund's investment objectives and strategies, as described in the Regulated Fund's registration statement on Form N–2, other filings the Regulated Fund has made with the Commission under the Securities Act of 1933 (the ''Securities Act''), or under the Securities Exchange Act of 1934 and the Regulated Fund's reports to shareholders.

companies that are typically backed by venture capital firms.

2. The board of directors of BDCA (the ''BDCA Board'') is comprised of five directors, three of whom are not ''interested persons,'' within the meaning of Section 2(a)(19) of the 1940 Act (the ''Non-Interested Directors''), of BDCA. The board of directors of BDCA II (the ''BDCA II Board'') is comprised of five directors, three of whom are Non-Interested Directors of BDCA II. The board of directors of BDCA Venture (the ''BDCA Venture Board,'' and collectively with the BDCA Board and the BDCA II Board, and any board of directors of a Future Regulated Fund, the ''Boards'' and each a ''Board,'' as applicable) consists of five directors, four of whom are Non-Interested Directors of BDCA Venture.

3. BDCA Adviser is a Delaware limited liability company that is registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''). BDCA Adviser serves as investment adviser to BDCA. BDCA Adviser II is a Delaware limited liability company that is registered as an investment adviser under the Advisers Act. BDCA Adviser II serves as investment adviser to BDCA II. BDCA Venture Adviser is a Delaware limited liability company that is registered as an investment adviser under the Advisers Act. BDCA Venture Adviser serves as investment adviser to BDCA Venture.

4. Applicants seek an order (''Order'') to permit a Regulated Fund [4] and one or more Regulated Funds and/or one or more Future Affiliated Funds [5] to participate in the same investment opportunities through a proposed co-investment program (the ''Co-Investment Program'') where such participation would otherwise be prohibited under section 57(a)(4) and rule 17d–1 by (a) co-investing with each other in securities issued by issuers in private placement transactions in which an Adviser negotiates terms in addition to price; [6] and (b) making additional investments in securities of such issuers, including through the exercise of warrants, conversion privileges, and other rights to purchase securities of the issuers (''Follow-On Investments''). ''Co-Investment Transaction'' means any transaction in which a Regulated Fund (or its Wholly-Owned Investment Sub, as defined below) participated together with one or more other Regulated Funds and/or one or more Future Affiliated Funds in reliance on the requested Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub, as defined below) could not participate together with one or more Future Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[7]

5. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.[8] Such a subsidiary would be prohibited from investing in a Co-Investment Transaction with any Future Affiliated Fund or Regulated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of its parent Regulated Fund and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the requested Order, as though the parent Regulated Fund were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Sub would have no purpose other than serving as a holding vehicle for the Regulated Fund's investments and, therefore, no conflicts of interest could arise between the Regulated Fund and the Wholly-Owned Investment Sub. The Regulated Fund's Board would make all relevant determinations under the conditions with regard to a Wholly-Owned Investment Sub's participation in a Co-Investment Transaction, and the Regulated Fund's Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Sub in the Regulated Fund's place. If the Regulated Fund proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subs, the Board will also be informed of, and take into consideration, the relative participation of the Regulated Fund and the Wholly-Owned Investment Sub.

6. When considering Potential Co-Investment Transactions for any Regulated Fund, the applicable Adviser will consider only the Objectives and Strategies, investment policies, investment positions, capital available for investment, and other pertinent factors applicable to that Regulated Fund. The Regulated Funds' Advisers expect that any portfolio company that is an appropriate investment for a Regulated Fund should also be an appropriate investment for one or more other Regulated Funds and/or one or more Future Affiliated Funds, with certain exceptions based on available capital or diversification.[9]

7. Other than pro rata dispositions and Follow-On Investments as provided in conditions 7 and 8, and after making the determinations required in conditions 1 and 2(a), the Adviser will present each Potential Co-Investment Transaction and the proposed allocation to the directors of the Board eligible to vote under section 57(o) of the Act (''Eligible Directors''), and the ''required majority,'' as defined in section 57(o) of the Act (''Required Majority'') [10] will approve each Co-Investment Transaction prior to any investment by the participating Regulated Fund.

8. With respect to the pro rata dispositions and Follow-On Investments provided in conditions 7 and 8, a Regulated Fund may participate in a pro rata disposition or Follow-On Investment without obtaining prior approval of the Required Majority if, among other things: (i) The proposed participation of each Regulated Fund and Future Affiliated Fund in such disposition is proportionate to its

[4] ''Regulated Fund'' means any of the BDCA Funds and any Future Regulated Fund. ''Future Regulated Fund'' means any closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC, (b) whose investment adviser is an Adviser, and (c) that intends to participate in the Co-Investment Program. The term ''Adviser'' means (a) BDCA Adviser, BDCA Adviser II, and BDCA Venture Adviser and (b) any future investment adviser that controls, is controlled by or is under common control with AR Capital, LLC and is registered as an investment adviser under the Advisers Act.

[5] ''Future Affiliated Fund'' means any entity (a) whose investment adviser is an Adviser, (b) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act, and (c) that intends to participate in the Co-Investment Program.

[6] The term ''private placement transactions'' means transactions in which the offer and sale of securities by the issuer are exempt from registration under the Securities Act.

[7] All existing entities that currently intend to rely upon the requested Order have been named as applicants. Any other existing or future entity that subsequently relies on the Order will comply with the terms and conditions of the application.

[8] The term ''Wholly-Owned Investment Sub'' means an entity (i) that is wholly-owned by a Regulated Fund (with the Regulated Fund at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of the Regulated Fund; (iii) with respect to which the Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the conditions of the Application; and (iv) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act.

[9] The Regulated Funds, however, will not be obligated to invest, or co-invest, when investment opportunities are referred to them.

[10] In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to Section 57(o).

outstanding investments in the issuer immediately preceding the disposition or Follow-On Investment, as the case may be; and (ii) the Board of the Regulated Fund has approved that Regulated Fund's participation in pro rata dispositions and Follow-On Investments as being in the best interests of the Regulated Fund. If the Board does not so approve, any such disposition or Follow-On Investment will be submitted to the Regulated Fund's Eligible Directors. The Board of any Regulated Fund may at any time rescind, suspend or qualify its approval of pro rata dispositions and Follow-On Investments with the result that all dispositions and/or Follow-On Investments must be submitted to the Eligible Directors.

9. No Non-Interested Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than through share ownership in one of the Regulated Funds.

**Applicants' Legal Analysis**

1. Section 57(a)(4) of the Act prohibits certain affiliated persons of a BDC from participating in joint transactions with the BDC or a company controlled by a BDC in contravention of rules as prescribed by the Commission. Under section 57(b)(2) of the Act, any person who is directly or indirectly controlling, controlled by, or under common control with a BDC is subject to section 57(a)(4). Applicants submit that each of the Regulated Funds and Future Affiliated Funds be deemed to be a person related to each Regulated Fund in a manner described by section 57(b) by virtue of being under common control. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Section 17(d) of the Act and rule 17d–1 under the Act prohibit affiliated persons of a registered investment company from participating in joint transactions with the company unless the Commission has granted an order permitting such transactions. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

3. Applicants state that in the absence of the requested relief, the Regulated Funds would be, in some circumstances, limited in their ability to participate in attractive and appropriate investment opportunities. Applicants believe that the proposed terms and conditions will ensure that the Co-Investment Transactions are consistent with the protection of each Regulated Fund's shareholders and with the purposes intended by the policies and provisions of the Act. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions will be consistent with the provisions, policies, and purposes of the Act and on a basis that is not different from or less advantageous than that of other participants.

4. Under condition 14, if the Advisers, the Principals, any person controlling, controlled by, or under common control with the Advisers or the Principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25% of the outstanding voting securities of a Regulated Fund (''Shares''), then the Holders will vote such Shares as directed by an independent third party when voting on matters specified in the condition. Applicants believe that this condition will ensure that the Non-Interested Directors will act independently in evaluating the Co-Investment Program, because the ability of the Advisers or the Principals to influence the Non-Interested Directors by a suggestion, explicit or implied, that the Non-Interested Directors can be removed will be limited significantly. Applicants represent that the Non-Interested Directors will evaluate and approve any such voting trust or proxy adviser, taking into accounts its qualifications, reputation for independence, cost to the shareholders, and other factors that they deem relevant.

**Applicants' Conditions**

Applicants agree that the Order will be subject to the following conditions:

1. Each time an Adviser considers a Potential Co-Investment Transaction for a Future Affiliated Fund or another Regulated Fund that falls within a Regulated Fund's then-current Objectives and Strategies, the Regulated Fund's Adviser will make an independent determination of the appropriateness of the investment for such Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. (a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the applicable Adviser to be invested by the applicable Regulated Fund in the Potential Co-Investment Transaction, together with the amount proposed to be invested by the other participating Regulated Funds and Future Affiliated Funds, collectively, in the same transaction, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on each participating party's capital available for investment in the asset class being allocated, up to the amount proposed to be invested by each. The applicable Adviser will provide the Eligible Directors of each participating Regulated Fund with information concerning each participating party's available capital to assist the Eligible Directors with their review of the Regulated Fund's investments for compliance with these allocation procedures.

(c) After making the determinations required in conditions 1 and 2(a), the applicable Adviser will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and Future Affiliated Fund) to the Eligible Directors of each participating Regulated Fund for their consideration. A Regulated Fund will co-invest with one or more other Regulated Funds and/or one or more Future Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the Potential Co-Investment Transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its shareholders and do not involve overreaching in respect of the Regulated Fund or its shareholders on the part of any person concerned;

(ii) the Potential Co-Investment Transaction is consistent with:

(A) The interests of the shareholders of the Regulated Fund; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Funds or Future Affiliated Funds would not disadvantage the Regulated Fund, and participation by

the Regulated Fund would not be on a basis different from or less advantageous than that of other Regulated Funds or Future Affiliated Funds; provided that, if any other Regulated Fund or Future Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors or the right to have a board observer or any similar right to participate in the governance or management of the portfolio company, such event shall not be interpreted to prohibit the Required Majority from reaching the conclusions required by this condition 2(c)(iii), if:

(A) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any;

(B) the applicable Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and

(C) any fees or other compensation that any Future Affiliated Fund or any Regulated Fund or any affiliated person of any Future Affiliated Fund or any Regulated Fund receives in connection with the right of an Future Affiliated Fund or a Regulated Fund to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among the participating Future Affiliated Funds (who each may, in turn, share its portion with its affiliated persons) and the participating Regulated Funds in accordance with the amount of each party's investment; and

(iv) the proposed investment by the Regulated Fund will not benefit the Advisers, the Future Affiliated Funds or the other Regulated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by condition 13, (B) to the extent permitted by sections 17(e) or 57(k) of the Act, as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in condition 2(c)(iii)(C).

3. Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. The applicable Adviser will present to the Board of each Regulated Fund, on a quarterly basis, a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or Future Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies that were not made available to the Regulated Fund, and an explanation of why the investment opportunities were not offered to the Regulated Fund. All information presented to the Board pursuant to this condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

5. Except for Follow-On Investments made in accordance with condition 8,[11] a Regulated Fund will not invest in reliance on the Order in any issuer in which another Regulated Fund, Future Affiliated Fund, or any affiliated person of another Regulated Fund or Future Affiliated Fund is an existing investor.

6. A Regulated Fund will not participate in any Potential Co-Investment Transaction unless the terms, conditions, price, class of securities to be purchased, settlement date, and registration rights will be the same for each participating Regulated Fund and Future Affiliated Fund. The grant to a Future Affiliated Fund or another Regulated Fund, but not the Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this condition 6, if conditions 2(c)(iii)(A), (B) and (C) are met.

7. (a) If any Future Affiliated Fund or any Regulated Fund elects to sell, exchange or otherwise dispose of an interest in a security that was acquired in a Co-Investment Transaction, the applicable Advisers will:

(i) Notify each Regulated Fund that participated in the Co-Investment Transaction of the proposed disposition at the earliest practical time; and

(ii) formulate a recommendation as to participation by each Regulated Fund in the disposition.

(b) Each Regulated Fund will have the right to participate in such disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the participating Future Affiliated Funds and Regulated Funds.

(c) A Regulated Fund may participate in such disposition without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Fund and each Future Affiliated Fund in such disposition is proportionate to its outstanding investments in the issuer immediately preceding the disposition; (ii) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such dispositions on a pro rata basis (as described in greater detail in the application); and (iii) the Board of the Regulated Fund is provided on a quarterly basis with a list of all dispositions made in accordance with this condition. In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

(d) Each Future Affiliated Fund and each Regulated Fund will bear its own expenses in connection with any such disposition.

8. (a) If any Future Affiliated Fund or any Regulated Fund desires to make a Follow-On Investment in a portfolio company whose securities were acquired in a Co-Investment Transaction, the applicable Advisers will:

(i) Notify each Regulated Fund that participated in the Co-Investment Transaction of the proposed transaction at the earliest practical time; and

(ii) formulate a recommendation as to the proposed participation, including the amount of the proposed Follow-On Investment, by each Regulated Fund.

(b) A Regulated Fund may participate in such Follow-On Investment without obtaining prior approval of the Required Majority if: (i) The proposed participation of each Regulated Fund and each Future Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer immediately preceding the Follow-On Investment; and (ii) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application). In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a

[11] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

Required Majority determines that it is in the Regulated Fund's best interests.

(c) If, with respect to any Follow-On Investment:

(i) The amount of the opportunity is not based on the Regulated Funds' and the Future Affiliated Funds' outstanding investments immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Adviser to be invested by each Regulated Fund in the Follow-On Investment, together with the amount proposed to be invested by the participating Future Affiliated Funds in the same transaction, exceeds the amount of the opportunity; then the amount invested by each such party will be allocated among them pro rata based on each participating party's capital available for investment in the asset class being allocated, up to the amount proposed to be invested by each.

(d) The acquisition of Follow-On Investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and subject to the other conditions set forth in the application.

9. The Non-Interested Directors of each Regulated Fund will be provided quarterly for review all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Future Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Non-Interested Directors may determine whether all investments made during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the conditions of the Order. In addition, the Non-Interested Directors will consider at least annually the continued appropriateness for the Regulated Fund of participating in new and existing Co-Investment Transactions.

10. Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these conditions were approved by the Required Majority under section 57(f) of the Act.

11. No Non-Interested Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise an ''affiliated person'' (as defined in the Act), of a Future Affiliated Fund.

12. The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective investment advisory agreements with Future Affiliated Funds and the Regulated Funds, be shared by the Regulated Funds and the Future Affiliated Funds in proportion to the relative amounts of the securities held or to be acquired or disposed of, as the case may be.

13. Any transaction fee [12] (including break-up or commitment fees but excluding broker's fees contemplated by section 17(e) or 57(k) of the Act, as applicable) received in connection with a Co-Investment Transaction will be distributed to the participating Regulated Funds and Future Affiliated Funds on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by such Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1) of the Act, and the account will earn a competitive rate of interest that will also be divided pro rata among the participating Regulated Funds and Future Affiliated Funds based on the amounts they invest in such Co-Investment Transaction. None of the Future Affiliated Funds, the Advisers, the other Regulated Funds or any affiliated person of the Regulated Funds or Future Affiliated Funds will receive additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction (other than (a) in the case of the Regulated Funds and the Future Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in condition 2(c)(iii)(C); and (b) in the case of an Adviser, investment advisory fees paid in accordance with the agreement between the Adviser and the Regulated Fund or Future Affiliated Fund.

14. If the Holders own in the aggregate more than 25% of the outstanding Shares, then the Holders will vote such Shares as directed by an independent third party (such as the trustee of a voting trust or a proxy adviser) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any matters requiring approval by the vote of a majority of the outstanding voting securities, as defined in Section 2(a)(42) of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11731 Filed 5–14–15; 8:45 am]

**BILLING CODE 8011–01–P**

[12] Applicants are not requesting and the staff is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 31597; File No. 812–14360]**

## The MainStay Funds, et al.; Notice of Application

May 11, 2015.

**AGENCY:** Securities and Exchange Commission (''Commission'').

**ACTION:** Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements.

**SUMMARY OF APPLICATION:** Applicants request an order that would permit them to enter into and materially amend subadvisory agreements with Wholly-Owned Subadvisers (as defined below) and Non-Affiliated Subadvisers (as defined below) without shareholder approval and would grant relief from certain disclosure requirements. The requested order would supersede a prior order that granted relief solely with respect to Non-Affiliated Subadvisers.[1]

**APPLICANTS:** The MainStay Funds, MainStay Funds Trust and MainStay VP Funds Trust (each, a ''Trust'') and New York Life Investment Management LLC (the ''Adviser'' or ''New York Life Investments'').

**FILING DATES:** The application was filed on September 19, 2014, and amended on February 3, 2015, and April 3, 2015.

**HEARING OR NOTIFICATION OF HEARING:** An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 5, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state

[1] The MainStay Funds, *et al.,* Investment Company Act Release Nos. 27595 (December 11, 2006) (notice) and 27656 (January 8, 2007) (order).

the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, c/o J. Kevin Gao, Esq., New York Life Investment Management LLC, 169 Lackawanna Avenue, Parsippany, New Jersey 07054.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth G. Miller, Senior Counsel, at (202) 551–8707, or Holly Hunter-Ceci, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

## Applicants' Representations

1. Each Trust is registered with the Commission as an open-end management investment company under the Act. Each of MainStay Funds Trust and MainStay VP Funds Trust is organized as a Delaware statutory trust, and The MainStay Funds is organized as a Massachusetts business trust. Each Trust may offer one or more series of shares (each a ''Fund,'' and collectively the ''Funds''), each with its own distinct investment objectives, policies and restrictions. Shares of MainStay VP Funds Trust will be offered and sold through insurance company accounts, which are used to fund variable annuity contracts. The Adviser is a Delaware limited liability company registered with the Commission as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''), and serves as investment adviser to the Funds.

2. Applicants request an order to permit the Adviser,[2] subject to the approval of the board of trustees of the applicable Trust (each a ''Board''),[3] including a majority of the trustees who are not ''interested persons'' of the Trusts or the Adviser, as defined in section 2(a)(19) of the Act (the ''Independent Trustees''), to, without obtaining shareholder[4] approval: (i) Select certain wholly-owned and non-affiliated investment Subadvisers[5] to manage all or a portion of the assets of one or more of the Funds pursuant to an investment subadvisory agreement with each Subadviser (each a ''Subadvisory Agreement'' and collectively, the ''Subadvisory Agreements''); and (ii) materially amend Subadvisory Agreements with the Subadvisers.[6] Applicants request that the relief apply to the named applicants, as well as to any future Fund and any other existing or future registered open-end management investment company or series thereof that intends to rely on the requested order in the future and (i) is advised by the Adviser or its successors; (ii) uses the multi-manager structure described in the application; and (iii) complies with the terms and conditions set forth in the application (each, a ''Subadvised Fund'').[7] The requested relief will not extend to any subadviser, other than a Wholly-Owned Subadviser, who is an affiliated person, as defined in section 2(a)(3) of the Act, of the Subadvised Funds or of the Adviser, other than by reason of serving as a subadviser to one or more of the Subadvised Funds (''Affiliated Subadviser'').

3. New York Life Investments serves as the investment adviser to each Fund pursuant to an investment advisory agreement with the applicable Trust (each an ''Investment Advisory Agreement'' and together the ''Investment Advisory Agreements''). Any future Adviser also will be registered with the Commission as an investment adviser under the Advisers Act. Each Investment Advisory Agreement has been or will be approved by the applicable Board, including a majority of the Independent Trustees, and by the shareholders of the relevant Fund in the manner required by sections 15(a) and 15(c) of the Act and rule 18f–2 thereunder. The terms of the Investment Advisory Agreements comply or will comply with section 15(a) of the Act.

4. Pursuant to the terms of each Investment Advisory Agreement, the Adviser, subject to the oversight of the applicable Board, has agreed or will agree to provide a continuous investment program for each Fund and determine the securities and other investments to be purchased, retained, sold or loaned by each Fund and the portion of such assets to be invested or held uninvested as cash. The Adviser will periodically review each Fund's investment policies and strategies and, based on the need of a particular Fund, may recommend changes to the investment policies and strategies of the Fund for consideration by the Board. For its services to each Fund, the Adviser receives or will receive an investment advisory fee from that Fund as specified in the applicable Investment Advisory Agreement. Consistent with the terms of each Subadvised Fund's Investment Advisory Agreement, the Adviser may, subject to the approval of the Board, including a majority of the Independent Trustees, and the shareholders of the applicable Subadvised Fund (if required), delegate portfolio management responsibilities of all or a portion of the assets of a Subadvised Fund to a Subadviser. The Adviser continues to have overall responsibility for the management and

[2] The term ''Adviser'' includes (1) New York Life Investments and (ii) any entity controlling, controlled by or under common control with, New York Life Investments or its successors. For the purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] The term ''Board'' also includes the board of trustees or directors of a future Subadvised Fund (as defined below), if different from the board of trustees of a Trust.

[4] The term ''shareholder'' includes variable contract owners and insurance companies entitled to give voting instructions with respect to a Fund. Pursuant to current Commission requirements and Commission staff interpretations, insurance companies vote Fund shares held in registered separate accounts in accordance with voting instructions received from variable contract owners or payees. In addition, Fund shares held in registered separate accounts for which contract owners or payees are entitled to give voting instructions, but as to which no voting instructions are received, are voted in proportion to the shares for which voting instructions have been received by that company. The term ''payee'' shall include an individual entitled to the receipt of payment under a variable annuity contract.

[5] A ''Subadviser'' for a Fund is a Subadviser that is (i) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the Adviser, or (ii) a sister company of the Adviser that is an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the same company that, indirectly or directly, wholly owns the Adviser (each of (i) and (ii) a ''Wholly-Owned Subadviser'' and collectively, the ''Wholly-Owned Subadvisers''), or (iii) not an ''affiliated person'' (as such term is defined in section 2(a)(3) of the Act) of the Funds, the applicable Trust, or the Adviser, except to the extent that an affiliation arises solely because the Subadviser serves as a subadviser to one or more Funds (each a ''Non-Affiliated Subadviser'' and collectively, the ''Non-Affiliated Subadvisers'').

[6] Shareholder approval will continue to be required for any other subadviser changes and material amendments to an existing subadvisory agreement with any subadviser other than a Non-Affiliated Subadviser or a Wholly-Owned Subadviser (all such changes referred to herein as ''Ineligible Subadviser Changes''), except as otherwise permitted by rule.

[7] All registered open-end investment companies that currently intend to rely on the requested order are named as applicants. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application. If the name of any Subadvised Fund contains the name of a Subadviser, the name of the Adviser that serves as the primary adviser to the Subadvised Fund, or a trademark or trade name that is owned by or publicly used to identify that Adviser, will precede the name of the Subadviser.

investment of the assets of each Subadvised Fund. These responsibilities include recommending the removal or replacement of Subadvisers, and determining the portion of that Subadvised Fund's assets to be managed by any given Subadviser and reallocating those assets as necessary from time to time.

5. Pursuant to the authority under the Investment Advisory Agreements, the Adviser may enter into Subadvisory Agreements with various Subadvisers on behalf of the Funds. The Adviser has entered into a Subadvisory Agreement with the following Subadvisers: Candriam Belgium S.A., Cornerstone Capital Management Holdings LLC; Cushing® Asset Management, LP; Eagle Asset Management, Inc.; Epoch Investments Partners, Inc.; Institutional Capital LLC; Janus Capital Management LLC; MacKay Shields LLC; Marketfield Asset Management LLC; Markston International LLC; Massachusetts Financial Services Company; NYL Investors LLC; Pacific Investment Management Company LLC; T. Rowe Price Associates, Inc.; Van Eck Associates Corporation; and Winslow Capital Management LLC. The Adviser also may, in the future, enter into Subadvisory Agreements with other Subadvisers on behalf of the Funds. The Subadvisory Agreements were or will be approved by the applicable Board, including a majority of the Independent Trustees, and the shareholders of the Subadvised Fund in accordance with sections 15(a) and 15(c) of the Act and rule 18f–2 thereunder. In addition, the terms of the Subadvisory Agreements comply or will comply fully with the requirements of section 15(a) of the Act. The Subadvisers, subject to the oversight of the Adviser and the applicable Board, determine or will determine the securities and other instruments to be purchased, sold or entered into by a Subadvised Fund's portfolio or a portion thereof, and place orders with brokers or dealers that they select. The Adviser will compensate the Subadvisers out of the fee received by the Adviser from the applicable Subadvised Fund under the applicable Investment Advisory Agreement.

6. Subadvised Funds will inform shareholders of the hiring of a new Subadviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) Within 90 days after a new Subadviser is hired for any Subadvised Fund, that Subadvised Fund will send its shareholders either a Multi-manager Notice or a Multi-manager Notice and Multi-manager Information Statement;[8] and (b) a Subadvised Fund will make the Multi-manager Information Statement available on the Web site identified in the Multi-manager Notice no later than when the Multi-manager Notice (or Multi-manager Notice and Multi-manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days. Applicants state that, in the circumstances described in the application, a proxy solicitation to approve the appointment of new Subadvisers provides no more meaningful information to shareholders than the proposed Multi-manager Information Statement. Applicants also state that the applicable Board would comply with the requirements of sections 15(a) and 15(c) of the Act before entering into or amending Subadvisory Agreements.

7. Applicants also request an order under section 6(c) of the Act exempting the Subadvised Funds from certain disclosure obligations that may require each Subadvised Fund to disclose fees paid by the Adviser to each Subadviser. Applicants seek relief to permit each Subadvised Fund to disclose (as a dollar amount and a percentage of a Subadvised Fund's net assets) (a) the aggregate fees paid to the Adviser and any Wholly-Owned Subadvisers; (b) the aggregate fees paid to Non-Affiliated Subadvisers; and (c) the fee paid to each Affiliated Subadviser (collectively, the ''Aggregate Fee Disclosure''). An exemption is requested to permit a Subadvised Fund to include only the Aggregate Fee Disclosure. All other items required by Sections 6–07(2)(a), (b) and (c) of Regulation S–X will be disclosed.

[8] A ''Multi-manager Notice'' will be modeled on a Notice of Internet Availability as defined in rule 14a–16 under the Securities Exchange Act of 1934 (''Exchange Act''), and specifically will, among other things: (a) Summarize the relevant information regarding the new Subadviser (except as modified to permit Aggregate Fee Disclosure, as defined below); (b) inform shareholders that the Multi-manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-manager Information Statement may be obtained, without charge, by contacting the Subadvised Fund.

A ''Multi-manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Exchange Act for an information statement, except as modified by the order to permit Aggregate Fee Disclosure. Multi-manager Information Statements will be filed with the Commission via the EDGAR system.

**Applicants' Legal Analysis**

1. Section 15(a) of the Act states, in part, that it is unlawful for any person to act as an investment adviser to a registered investment company ''except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company.'' Rule 18f–2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the ''advisory fee payable'' by the investment company, including the total dollar amounts that the investment company ''paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years.''

3. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the Exchange Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fee,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b) and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such

exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that their requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to the review and approval of the applicable Board, to select a Subadviser who is in the best position to achieve the Subadvised Fund's investment objective. Applicants assert that, from the perspective of the shareholder, the role of the Subadvisers is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of a Subadvised Fund are paying the Adviser—the selection, supervision and evaluation of the Subadviser—without incurring unnecessary delays or expenses is appropriate and in the interest of a Subadvised Fund's shareholders and will allow such Subadvised Fund to operate more efficiently. Applicants state that each Investment Advisory Agreement will continue to be fully subject to section 15(a) of the Act and rule 18f–2 under the Act and approved by the relevant Board, including a majority of the Independent Trustees, in the manner required by sections 15(a) and 15(c) of the Act. Applicants are not seeking an exemption with respect to the Investment Advisory Agreements.

7. Applicants assert that disclosure of the individual fees that the Adviser would pay to the Subadvisers does not serve any meaningful purpose. Applicants contend that the primary reasons for requiring disclosure of individual fees paid to Subadvisers are to inform shareholders of expenses to be charged by a particular Subadvised Fund and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the advisory fee paid to the Adviser will be fully disclosed and, therefore, shareholders will know what a Subadvised Fund's fees and expenses are and will be able to compare the advisory fees a Subadvised Fund is charged to those of other investment companies. Applicants assert that the requested disclosure relief would benefit shareholders of the Subadvised Funds because it would improve the Adviser's ability to negotiate the fees paid to Subadvisers. Applicants state that the Adviser may be able to negotiate rates that are below a Subadviser's ''posted'' amounts if the Adviser is not required to disclose the Subadvisers' fees to the public. Applicants assert that the relief will also encourage Subadvisers to negotiate lower subadvisory fees with the Adviser if the lower fees are not required to be made public.

8. Applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act. Applicants state that the operation of a Subadvised Fund in the manner described in the application must be approved by shareholders of the Subadvised Fund before that Subadvised Fund may rely on the requested order. In addition, applicants state that any conflict of interest or economic incentive that may exist in connection with the Adviser selecting a Wholly-Owned Subadviser to manage all or a portion of the assets of a Subadvised Fund are addressed under the terms and conditions of the application and will be disclosed to shareholders and considered by the applicable Board when it reviews the selection or termination of Subadvisers. Applicants also assert that conditions 6, 7, 10 and 11 are designed to provide the Board with sufficient independence and the resources and information it needs to monitor and address any conflicts of interest. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

**Applicants' Conditions**

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Subadvised Fund may rely on the order requested in the application, the operation of the Subadvised Fund in the manner described in the application, including the hiring of Wholly-Owned Subadvisers, will be, or has been, approved by a majority of the Subadvised Fund's outstanding voting securities (or if the Subadvised Fund serves as a funding medium for any sub-account of a registered separate account, pursuant to voting instructions provided by variable contract owners with to whom units of the sub-account are credited), as defined in the Act, or, in the case of a Subadvised Fund whose public shareholders (or variable contract owners through a registered separate account) purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder before such Subadvised Fund's shares are offered to the public (or the variable contract owners through a separate account).

2. The prospectus for each Subadvised Fund will disclose the existence, substance, and effect of any order granted pursuant to the application. In addition, each Subadvised Fund will hold itself out to the public as employing the multi-manager structure described in the application. The prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the applicable Board, to oversee the Subadvisers and recommend their hiring, termination and replacement.

3. The Adviser will provide general management services to each Subadvised Fund, including overall supervisory responsibility for the general management and investment of the Subadvised Fund's assets, and subject to review and approval of the applicable Board, will (i) set the Subadvised Fund's overall investment strategies; (ii) evaluate, select, and recommend Subadvisers to manage all or a portion of the Subadvised Fund's assets; (iii) allocate and, when appropriate, reallocate the Subadvised Fund's assets among Subadvisers; (iv) monitor and evaluate the Subadvisers' performance; and (v) implement procedures reasonably designed to ensure that Subadvisers comply with the Subadvised Fund's investment objective, policies and restrictions.

4. A Subadvised Fund will not make any Ineligible Subadviser Changes without the approval of the shareholders (or, if the Subadvised Fund serves as a funding medium for any sub-account of a registered separate account, the Adviser will inform the unitholders of the sub-account) of the applicable Subadvised Fund.

5. Subadvised Funds will inform shareholders (or, if the Subadvised Fund serves as a funding medium for any sub-account of a registered separate account, the Adviser will inform the unitholders of the sub-account) of the hiring of a new Subadviser within 90 days after the hiring of the new Subadviser pursuant to the Modified Notice and Access Procedures.

6. At all times, at least a majority of the applicable Board will be Independent Trustees, and the selection and nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

7. Independent Legal Counsel, as defined in rule 0–1(a)(6) under the Act,

will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

8. The Adviser will provide the applicable Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Subadvised Fund basis. The information will reflect the impact on profitability of the hiring or termination of any Subadviser during the applicable quarter.

9. Whenever a Subadviser is hired or terminated, the Adviser will provide the applicable Board with information showing the expected impact on the profitability of the Adviser.

10. Whenever a Subadviser change is proposed for a Subadvised Fund with an Affiliated Subadviser or a Wholly-Owned Subadviser, the applicable Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the applicable Board minutes, that the change is in the best interests of the Subadvised Fund and its shareholders and does not involve a conflict of interest from which the Adviser or the Affiliated Subadviser or Wholly-Owned Subadviser derives an inappropriate advantage.

11. No Trustee or officer of a Subadvised Fund, or director, manager or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person), any interest in a Subadviser except for (a) ownership of interests in the Adviser or any entity, other than a Wholly-Owned Subadviser, that controls, is controlled by or is under common control with the Adviser, or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly-traded company that is either a Subadviser or an entity that controls, is controlled by, or is under common control with a Subadviser.

12. Each Subadvised Fund will disclose in its registration statement the Aggregate Fee Disclosure.

13. In the event that the Commission adopts a rule under the Act providing substantially similar relief to that requested in the application, the requested order will expire on the effective date of that rule.

14. Any new Subadvisory Agreement or any amendment to a Subadvised Fund's existing investment advisory agreement or Subadvisory Agreement that directly or indirectly results in an increase in the aggregate advisory fee rate payable by the Subadvised Fund will be submitted to the Subadvised Fund's shareholders (or, if the Subadvised Fund serves as a funding medium for any sub-account of a registered separate account, the Adviser will inform the unitholders of the sub-account) for approval.

For the Commission, by the Division of Investment Management, under delegated authority.

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11730 Filed 5–14–15; 8:45 am]

**BILLING CODE 8011–01–P**

---

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–74922; File No. SR–ICEEU–2015–009]**

## Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Finance Procedures To Add Clearstream Banking as a Triparty Collateral Service Provider

May 11, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder [2] notice is hereby given that on May 5, 2015, ICE Clear Europe Limited (''ICE Clear Europe'') 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 primarily prepared by ICE Clear Europe. 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

ICE Clear Europe proposes amendments to its Finance Procedures in order to facilitate the use by CDS Clearing Members of Clearstream Banking as a triparty collateral service provider.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe 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*

The purpose of the proposed rule change is to modify the Finance Procedures to allow Clearstream Banking to serve as a triparty collateral service provider for initial or original margin provided in respect of all product categories, including CDS Contracts. (Clearstream Banking currently serves as a triparty collateral service provider solely for original margin provided in respect of F&O Contracts).

Specifically, paragraph 3.1 of the Finance Procedures is revised to remove the existing restriction that Clearstream Banking may only act as a triparty collateral service provider with respect to Original Margin in respect of F&O Contracts. As a result of such change, Clearstream Banking would be permitted to act as a triparty collateral service provider for initial or original margin in respect of any product category, including the CDS product category. (The other currently authorized triparty collateral service provider, Euroclear Bank, is similarly eligible to act as such for any product category.) A correction is also made in paragraph 3.20 to provide that the specified instruction deadlines apply to triparty collateral arrangements with both Euroclear Bank and Clearstream Banking.

ICE Clear Europe believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [3] and the regulations thereunder applicable to it. Section 17A(b)(3)(F) of the Act [4] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.

The proposed amendments are intended to extend the Clearing House's existing triparty collateral service to allow optional use by Clearing Members of Clearstream Banking as a triparty collateral service provider with respect to initial and original margin for the CDS (and FX) product categories, in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78q–1.

[4] 15 U.S.C. 78q–1(b)(3)(F).

addition to its existing authorization for the F&O product category. The amendments do not otherwise change the substantive terms of the service. ICE Clear Europe views Clearstream Banking as substantially similar to Euroclear Bank, the current service provider, from an operational and risk perspective and otherwise in terms of the safeguarding of funds and securities. Clearstream Banking is currently authorized to act as a triparty collateral service provider with respect to original margin for the F&O product category, and based on experience in that product category ICE Clear Europe believes that use of Clearstream Banking can be appropriately extended to the other product categories. As a result, ICE Clear Europe believes that the proposed rule change will not adversely affect the safeguarding of securities or funds in the custody or control of ICE Clear Europe or for which it is responsible, and are therefore consistent with the requirements of Section 17A(b)(3)(F).[5]

*B. Self-Regulatory Organization's Statement on Burden on Competition*

ICE Clear Europe does not believe the proposed rule change would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will provide additional flexibility to Clearing Members by permitting the use, on a voluntary basis, of Clearstream Banking as a triparty collateral service provider for original or initial margin for all product categories. The proposed rule change will otherwise not affect the terms or conditions of any cleared contract or the standards or requirements for participation in or use of the Clearing House. Accordingly, the proposed rule change should not, in the Clearing House's view, affect the availability of clearing, access to clearing services or the costs of clearing for clearing members or other market participants.

*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 been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

[5] 15 U.S.C. 78q–1(b)(3)(F).

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate 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 or disapprove the 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 email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2015–009 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2015–009. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's Web site at *https://www.theice.com/clear-europe/regulation.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2015–009 and should be submitted on or before June 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11715 Filed 5–14–15; 8:45 am]

**BILLING CODE 8011–01–P**

[6] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

### Submission for OMB Review; Comment Request

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

*Extension:*

Form N–6, SEC File No. 270–446, OMB Control No. 3235–0503.

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 (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

The title for the collection of information is ''Form N–6 (17 CFR 239.17c and 274.11d) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) and under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) registration statement of separate accounts organized as unit investment trusts that offer variable life insurance policies.'' Form N–6 is the form used by insurance company separate accounts organized as unit investment trusts that offer variable life insurance contracts to register as investment companies under the Investment Company Act of 1940 and/or to register their securities under the Securities Act of 1933. The primary purpose of the registration process is to provide disclosure of financial and other information to investors and potential investors for the purpose of

evaluating an investment in a security. Form N–6 also requires separate accounts organized as unit investment trusts that offer variable life insurance policies to provide investors with a prospectus and a statement of additional information (''SAI'') covering essential information about the separate account when it makes an initial or additional offering of its securities.

The Commission estimates that approximately 472 registration statements (396 post-effective amendments plus 76 initial registration statements) are filed on Form N–6 annually. The estimated hour burden per portfolio for preparing and filing an initial registration statement on Form N–6 is 770.25 hours. The estimated annual hour burden for preparing and filing initial registration statements is 58,539 hours (76 initial registration statements annually times 770.25 hours per registration statement). The Commission estimates that the hour burden for preparing and filing a post-effective amendment on Form N–6 is 67.5 hours. The total annual hour burden for preparing and filing post-effective amendments is 26,730 hours (396 post-effective amendments annually times 67.5 hours per amendment). The frequency of response is annual. The total annual hour burden for Form N–6, therefore, is estimated to be 85,269 hours (58,539 hours for initial registration statements plus 26,730 hours for post-effective amendments).

The Commission estimates that the cost burden for preparing an initial Form N–6 filing is $24,169 per portfolio and the current cost burden for preparing a post-effective amendment to a previously effective registration statement is $8,788 per portfolio. The Commission estimates that, on an annual basis, 76 portfolios will be referenced in an initial Form N–6 and 396 portfolios will be referenced in a post-effective amendment of Form N–6. Thus, the total cost burden allocated to Form N–6 would be $5,316,892.

The information collection requirements imposed by Form N–6 are mandatory. Responses to the collection of information will not be kept confidential. Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. 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.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (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 by sending an email to: *Shagufta_Ahmed@omb.eop.gov*; and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: May 11, 2015.

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015–11729 Filed 5–14–15; 8:45 am]

BILLING CODE 8011–01–P

## SMALL BUSINESS ADMINISTRATION

### SBIR/STTR Logo Design Competition Announcement; Correction

The Small Business Administration published a document in the **Federal Register** of May 5, 2015 (Vol. 80, No. 86, Pages 25763–25765), concerning the announcement of a competition to design a logo for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs. This document was corrected (with scheduled publication of May 11, 2015) to reflect the fact that the competition was only going to be judged by SBA Officials and other SBIR/STTR Program Managers.

The initial and corrected documents did not include a monetary prize to be awarded to the winner. By way of this memo, SBA has made a determination that the document needs to be corrected again to include a prize of $2,500.

In the document printed on May 5, 2015, the first full sentence on page 25764 under the caption: ''4. *Prizes for Winners'' did not include the mentioning of any monetary prize for the winner.* This reference should be corrected and the sentence should read:

4. *Prizes for Winners: The winning contestant will be awarded a $2,500 prize and the* design will become the official logo for the SBIR/STTR Programs, the Programs' Web site at *sbir.gov,* and any official SBA, SBIR Program and/or STTR Program purpose.

**John R. Williams,**

*Director, Office of Innovation and Technology.*

[FR Doc. 2015–11697 Filed 5–14–15; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

### Data Collection Available for Public Comments

**ACTION:** 60-Day notice and request for comments.

**SUMMARY:** The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the new collection of information described below. The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. Chapter 35 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

**DATES:** Submit comments on or before July 14, 2015.

**ADDRESSES:** Send all comments to Delcine Montgomery, Contracting Officer Technical Representative, Office of Native American Affairs, U.S. Small Business Administration, 409 3rd Street SW., Suite 6700, Washington, DC 20416.

**FOR FURTHER INFORMATION CONTACT:** Delcine Montgomery, Contracting Officer Technical Representative, 202–205–6195 or *delcine.montgomery@sba.gov.,* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

**SUPPLEMENTARY INFORMATION:** In October 2013, the SBA's Office of the Native Business Development awarded a contract to Cherokee Nation Technology Solutions, LLC (CNTS) to provide 8(a) Business Development Program training to American Indian Tribes (AITs) Alaskan Native Corporations (ANCs) and Native Hawaiian Organizations (NHOs). The primary purpose of Native American 8(a) Business Development Program Workshops Training Initiative (the Native American 8(a) BD Workshops) is to improve the Native American business owners and entrepreneur's understanding of the SBA 8(a) Business Development program's eligibility requirements and application process, business operation features for successful contract management, revenue-generating/job-

creating capabilities as a tribal 8(a) certified federal contractor.

SBA plans to conduct a performance evaluation of the Native American 8(a) BD Workshops to assess the training services provided to individuals who directly and indirectly obtained the information and knowledge from the workshops, the preliminary impact of training on the business goals of direct and indirect participants, participant satisfaction with the training provider, and lessons learned and recommendations by the CNTS and the participants in the workshops. One unique feature of the implementation of the Native American 8(a) BD Workshops is that a significant number of participants were representing tribal organizations such as Leadership, Tribal Council, and Economic/Business Development. With the participation of the tribal representatives, there is a strong possibility that the knowledge learned from Native American 8(a) BD Workshops could be further disseminated by these tribal representatives to the other members/business owners of the tribes. Therefore, SBA plans to enhance and increase the data collection of performance metrics and collect survey data from participants who attended the workshops and the individuals who indirectly obtained the related knowledge from the tribal representatives. These data will facilitate the comprehensive assessment of Native American 8(a) BD workshop operations, outcomes and impacts.

Specifically, SBA proposes the use of two different instruments for data collection and analysis: (1) The Native American 8(a) Business Development Program Workshops Training Initiative Direct Participant Survey; and (2) the Native American 8(a) Business Development Program Workshops Training Initiative Indirect Participant Survey. Both of the surveys will be administered electronically and will contain both open- and close-ended questions. The types of information that will be collected in the instruments can be found in the ''Summary of Information Collection'' section below. Both quantitative and qualitative data analyses will be conducted. Quantitative analysis will consist of univariate and multivariate statistical techniques to summarize surveys results and explore the relationships among various data elements. The qualitative analysis will consist of identifying and interpreting themes for the open-ended survey questions. The information collected and analyzed from the survey instruments will be used to develop performance metrics, establish the achievement of the program's goals as well as providing recommendations on improving program operations.

**(a) Solicitation of Public Comments**

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

**(b) Summary of Information Collection**

*1. Native American 8(a) Business Development Program Workshops Training Initiative Direct Participant Outcome Survey*

*Description and Number of Respondents:* The web surveys will be conducted with participants who directly attended Native American 8(a) BD Program Workshops in FY2014. The direct participant survey will be provided to a total of 422 direct participants who attended the workshops in all 31 locations during FY2014. SBA is anticipating a 25% response rate and, as a result, it's estimated that 105 direct workshop participants will complete the Native American 8(a) BD direct participant web survey.

The direct participants survey will consist of questions about the demographics of participants, their business characteristics, needs and goals, whether the workshop staff effectively assessed their business needs before conducting the training services, the types of training received, the training resources other than Native American 8(a) BD Workshops that they used, participant outcomes, impact of training, and participant satisfaction with the workshops.

*Estimated Responses and Hour Burden:* The total estimated number of responses to the survey will be 105 at an estimated average completion time is approximately 28 minutes. The total estimated annual hour burden is 506.22 for the Native American 8(a) BD Workshops Direct Participant Outcome Survey. It includes the hour burden (48.3 hours) to the 105 respondents for completing the web survey, receiving thank you letters after completion of the survey, the hours burden for the pretesting conducted with 8 participants, as well as multiple contacts with all 422 potential respondents, such as the announcement from directors, the survey invite, the reminder email from the directors, the reminder email from community leaders, and three reminder emails. The total annual burden also includes compiling the indirect participant list by tribal representatives who attended the workshop and the burden of sending the survey announcement letter by the tribal representatives to the indirect participants.

*2. Native American 8(a) Business Development Program Workshops Training Initiative Indirect Participant Outcome Survey*

*Description and Number of Respondents:* The web surveys will be conducted with Native American business owners and entrepreneurs who did not attend Native American 8(a) Business Development Program Workshops in FY2014, but obtained the knowledge and information related to the Native American 8(a) BD Program from the tribal representatives. SBA estimates that the sample size for indirect participants will be 275, based on 110 tribal representatives attending the workshops, the 25% response rate, and an average of 10 indirect participants per a tribal representative. The response rate for these 275 potential respondents is estimated to be 25%, resulting in the sample size of 69 completed the surveys. The indirect participant's survey will consist of questions about the demographics of participants as well as their business characteristics, needs and goals, the information they received, the business assistance resources they used, business outcomes, impact of obtained information, and their satisfaction with the obtained information.

*Estimated Responses and Hour Burden:* The total estimated number of responses from this survey will be 69. The estimated average completion time of a survey is approximately 25 minutes. The total estimated annual hour burden is 166.5. In addition to the hour burden (*i.e.* 28.98 hours) to the 69 respondents for completing the indirect participant outcome survey, this annual hour burden (*i.e.* 166.5 hours) also includes the burden of 275 program indirect participants reading the announcement email from tribal organization representatives, reading survey invite and four reminder emails and 69 respondents receiving thank you letters after completion of the survey.

*Total Estimated Respondents for both survey instruments:* 174, including 105 direct participants and 69 indirect participants.

*Total Estimated Annual Hour Burden for both survey instruments:* Approximately 672.72 hours.

**Curtis B. Rich,**

*Management Analyst.*

[FR Doc. 2015–11699 Filed 5–14–15; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #14301 and #14302]**

### Florida Disaster #FL–00105

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Administrative declaration of a disaster for the State of Florida dated 05/08/2015.

*Incident:* Tornado.

*Incident Period:* 04/25/2015.

*Effective Date:* 05/08/2015.

*Physical Loan Application Deadline Date:* 07/07/2015.

*Economic Injury (EIDL) Loan Application Deadline Date:* 02/08/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Duval.

*Contiguous Counties:*

Florida: Baker, Clay, Nassau, Saint Johns.

The Interest Rates are:

| | Percent |
|---|---|
| *For Physical Damage:* | |
| Homeowners With Credit Available Elsewhere | 3.375 |
| Homeowners Without Credit Available Elsewhere | 1.688 |
| Businesses With Credit Available Elsewhere | 6.000 |
| Businesses Without Credit Available Elsewhere | 4.000 |
| Non-Profit Organizations With Credit Available Elsewhere | 2.625 |
| Non-Profit Organizations Without Credit Available Elsewhere | 2.625 |
| *For Economic Injury:* | |
| Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere | 4.000 |
| Non-Profit Organizations Without Credit Available Elsewhere | 2.625 |

The number assigned to this disaster for physical damage is 14301 C and for economic injury is 14302 0.

The State which received an EIDL Declaration # is Florida.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: May 8, 2015.

**Maria Contreras-Sweet,**

*Administrator.*

[FR Doc. 2015–11696 Filed 5–14–15; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #14261 and #14262]**

### Tennessee Disaster Number TN–00087

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 2.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Tennessee (FEMA–4211–DR), dated 04/02/2015.

*Incident:* Severe winter storm and flooding.

*Incident Period:* 02/15/2015 through 02/22/2015.

*Effective Date:* 05/07/2015.

*Physical Loan Application Deadline Date:* 06/01/2015.

*Economic Injury (EIDL) Loan Application Deadline Date:* 01/04/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration Processing, and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster declaration for private non-profit organizations in the State of Tennessee, dated 04/02/2015, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Counties:* Claiborne, Cocke, Davidson, Dekalb, Greene, Hawkins, Pickett, Rhea, Wayne.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2015–11698 Filed 5–14–15; 8:45 am]

BILLING CODE 8025–01–P

## SUSQUEHANNA RIVER BASIN COMMISSION

### Projects Approved for Consumptive Uses of Water

**AGENCY:** Susquehanna River Basin Commission.

**ACTION:** Notice.

**SUMMARY:** This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

**DATES:** February 1–28, 2015.

**ADDRESSES:** Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

**FOR FURTHER INFORMATION CONTACT:** Jason E. Oyler, Regulatory Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net* . Regular mail inquiries may be sent to the above address.

**SUPPLEMENTARY INFORMATION:** This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

**Approvals by Rule Issued Under 18 CFR 806.22(f)**

1. Chesapeake Appalachia, LLC, Pad ID: Duane, ABR–20100601.R1, Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.
2. Chesapeake Appalachia, LLC, Pad ID: Finnerty, ABR–20100602.R1, West Burlington Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.
3. Chesapeake Appalachia, LLC, Pad ID: Allen, ABR–20100606.R1, Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.
4. Chesapeake Appalachia, LLC, Pad ID: Rylee, ABR–20100610.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.
5. Chesapeake Appalachia, LLC, Pad ID: Stalford, ABR–20100617.R1, Wyalusing Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

6. Chesapeake Appalachia, LLC, Pad ID: Shaw, ABR–20100634.R1, Windham Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

7. Chesapeake Appalachia, LLC, Pad ID: Cannella, ABR–20100637.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

8. Chesapeake Appalachia, LLC, Pad ID: BDF, ABR–20100640.R1, Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

9. Chesapeake Appalachia, LLC, Pad ID: Akita NEW, ABR–20100689.R1, Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

10. Chesapeake Appalachia, LLC, Pad ID: Hilltop NEW, ABR–201006102.R1, Jessup Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

11. Chesapeake Appalachia, LLC, Pad ID: Kipar NEW, ABR–201006107.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

12. Chesapeake Appalachia, LLC, Pad ID: Curtain NEW, ABR–201006110.R1, Windham Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 2, 2015.

13. Carrizo (Marcellus), LLC, Pad ID: Baker 2H, ABR–201008137.R1, Forest Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 1.400 mgd; Approval Date: March 10, 2015.

14. SWEPI, LP, Pad ID: Cascarino 443, ABR–20100222.R1, Shippen Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 10, 2015.

15. Chesapeake Appalachia, LLC, Pad ID: Bonin, ABR–20100639.R1, Orwell Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 13, 2015.

16. Chesapeake Appalachia, LLC, Pad ID: Alderfer NEW, ABR–20100671.R1, Litchfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 13, 2015.

17. Chesapeake Appalachia, LLC, Pad ID: Cranrun, ABR–20100680.R1, Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 13, 2015.

18. Chesapeake Appalachia, LLC, Pad ID: Black Creek, ABR–20100686.R1, Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 13, 2015.

19. Chesapeake Appalachia, LLC, Pad ID: Beebe, ABR–20100687.R1, Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 13, 2015.

20. Chesapeake Appalachia, LLC, Pad ID: Linski, ABR–20100662.R1, Tuscarora Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 16, 2015.

21. Chesapeake Appalachia, LLC, Pad ID: Lillie-NEW, ABR–201006104.R1, Herrick Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 16, 2015.

22. Chesapeake Appalachia, LLC, Pad ID: Jacobs, ABR–201007028.R1, Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 16, 2015.

23. Chesapeake Appalachia, LLC, Pad ID: Dewees, ABR–201007063.R1, Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 16, 2015.

24. Chesapeake Appalachia, LLC, Pad ID: Towner, ABR–20100638.R1, Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 17, 2015.

25. Chesapeake Appalachia, LLC, Pad ID: Them, ABR–20100642.R1, Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 17, 2015.

26. Chesapeake Appalachia, LLC, Pad ID: Rowe, ABR–201007101.R1, Rome Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 17, 2015.

27. Range Resources—Appalachia, LLC, Pad ID: Shohocken Hunt Club Unit #1H–#6H, ABR–20100646.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: March 17, 2015.

28. SWEPI, LP, Pad ID: Sharretts 805, ABR–20100229.R1, Clymer Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 17, 2015.

29. SWEPI, LP, Pad ID: Parthemer 284, ABR–20100311.R1, Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: March 17, 2015.

30. XTO Energy Incorporated, Pad ID: Hazlak 8504, ABR–20100211.R1, Shrewsbury Township, Lycoming County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: March 17, 2015.

31. Chesapeake Appalachia, LLC, Pad ID: Henderson, ABR–201006103.R1, Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 20, 2015.

32. Chesapeake Appalachia, LLC, Pad ID: Coveytown, ABR–201007014.R1, Cherry Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 20, 2015.

33. Chesapeake Appalachia, LLC, Pad ID: Insinger, ABR–201007023.R1, Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 20, 2015.

34. Range Resources—Appalachia, LLC, Pad ID: Ogontz 41H–43H, ABR–201503001, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: March 20, 2015.

35. Range Resources—Appalachia, LLC, Pad ID: Laurel Hill 17H–22H, ABR–201503002, Jackson Township, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: March 20, 2015.

36. Range Resources—Appalachia, LLC, Pad ID: Laurel Hill D Pad, ABR–201503003, Cogan House and Jackson Townships, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: March 23, 2015.

37. SWN Production Company, LLC, Pad ID: NR–24 BUCKHORN–PAD, ABR–201503004, Oakland Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: March 27, 2015.

38. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 231 C, ABR–20100304.R1, Boggs Township, Centre County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

39. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 342 D, ABR–20100349.R1, Beech Creek Township, Clinton County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

40. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 231 D, ABR–20100530.R1, Snow Shoe Township, Centre County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

41. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 289 C, ABR–20100636.R1, McHenry Township, Lycoming County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

42. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 342 A, ABR–20100695.R1, Beech Creek Township, Clinton County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

43. Cabot Oil & Gas Corporation, Pad ID: DavisG P1, ABR–201007120.R1, Gibson Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 30, 2015.

44. Cabot Oil & Gas Corporation, Pad ID: AdamsJ P1, ABR–201007121.R1, Harford Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 30, 2015.

45. Cabot Oil & Gas Corporation, Pad ID: PlonskiJ P1, ABR–201008009.R1, Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 30, 2015.

46. Cabot Oil & Gas Corporation, Pad ID: Maiolini P3, ABR–201008114.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 30, 2015.

47. Cabot Oil & Gas Corporation, Pad ID: StockholmK P2, ABR–201008134.R1, Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: March 30, 2015.

48. Cabot Oil & Gas Corporation, Pad ID: HallidayA P1, ABR–201503005, Bridgewater Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.250 mgd; Approval Date: March 30, 2015.

49. Cabot Oil & Gas Corporation, Pad ID: BolcatoG P1, ABR–201503006, Gibson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.250 mgd; Approval Date: March 30, 2015.

50. Chesapeake Appalachia, LLC, Pad ID: Lopatofsky NEW, ABR–201007100.R1, Washington Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 30, 2015.

51. Chesapeake Appalachia, LLC, Pad ID: Slumber Valley, ABR–201008015.R1, Meshoppen Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: March 30, 2015.

52. Chief Oil & Gas, LLC, Pad ID: Allen Drilling Pad #1, ABR–201009002.R1, Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 2.000 mgd; Approval Date: March 30, 2015.

53. Chief Oil & Gas, LLC, Pad ID: Hemlock Hunting Club Drilling Pad #1, ABR–201009070.R1, Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 2.000 mgd; Approval Date: March 30, 2015.

54. EXCO Resources (PA), LLC, Pad ID: Confer (Pad 32), ABR–20100669.R1, Burnside Township, Centre County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: March 30, 2015.

55. SWEPI LP, Pad ID: Paul 906, ABR–20100314.R1, West Branch Township, Potter County, Pa.; Consumptive Use of Up to 4.990 mgd; Approval Date: March 30, 2015.

56. SWEPI LP, Pad ID: Waskiewicz 445, ABR–20100330.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 1.000 mgd; Approval Date: March 30, 2015.

57. SWEPI LP, Pad ID: Webster 549, ABR–20100335.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 1.000 mgd; Approval Date: March 30, 2015.

58. XTO Energy Incorporated, Pad ID: Dietterick, ABR–20100315.R1, Jordan Township, Lycoming County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: March 30, 2015.

**Authority:** Pub. L. 91–575, 84 Stat. 1509, *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: May 11, 2015.

**Stephanie L. Richardson,**

*Secretary to the Commission.*

[FR Doc. 2015–11673 Filed 5–14–15; 8:45 am]

BILLING CODE 7040–01–P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Notice of Final Federal Agency Actions on Proposed Highways in Colorado

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

**SUMMARY:** This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to various proposed highway projects in the State of Colorado. Those actions grant licenses, permits, and approvals for the projects.

**DATES:** By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on any of the listed highway projects will be barred unless the claim is filed on or before October 13, 2015. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Gibson, Environmental Program Manager, Federal Highway Administration Colorado Division, 12300 W. Dakota Avenue, Lakewood, Colorado 80228, 720–963–3013, *Stephanie.gibson@dot.gov* normal business hours are 8:30 a.m. to 5:00 p.m. (Mountain time); You may also contact Vanessa Henderson, NEPA Program Manager, Colorado Department of Transportation, 4201 E. Arkansas Avenue, Shumate Building, Denver, Colorado 80222, 303–757–9878, *vanessa.henderson@state.co.us,* normal business hours are 7:00 a.m. to 4:30 p.m. (Mountain time).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Colorado that are listed below. The actions by the Federal agencies on a project, and the laws under which such actions were taken, are described in the environmental assessment (EA) or environmental impact statement (EIS) issued in connection with the project and in other key project documents. The EA or EIS, and other key documents for the listed projects are available by contacting the FHWA or the Colorado Department of Transportation at the addresses provided above. The EA, Finding of No Significant Impact (FONSI), Final EIS, and Record of Decision (ROD) documents can be viewed and downloaded from the Web sites listed below.

This notice applies to all Federal agency decisions on each project as of the issuance date of this notice and all laws under which such actions were taken. This notice does not, however, alter or extend the limitation period of 150 days for challenges to final agency actions subject to previous notices published in the **Federal Register**, including notice given by the Federal Transit Administration on September 23, 2010 related to U.S. 36 (75 FR 58017).

This notice applies to all Federal agency decisions, actions, approvals, licenses and permits on the project as of the issuance date of this notice, including but not limited to those arising under the following laws, as amended:

1. General: National Environmental Policy Act [42 U.S.C. 4321–4370h]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Air: Clean Air Act, as amended [42 U.S.C. 7401–7671(q)] (transportation conformity).

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(e)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966 [54 U.S.C. 306108]; Archaeological Resources Protection Act of 1977 [16 U.S.C. 470aa–

470mm]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469c–2]; Native American Grave Protection and Repatriation Act [25 U.S.C. 3001–3013].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act [7 U.S.C. 4201–4209]; the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 [42 U.S.C. 61].

7. Wetlands and Water Resources: Clean Water Act [33 U.S.C. 1251–1387] (Section 404, Section 401, Section 319); Land and Water Conservation Fund Act [16 U.S.C. 460l–4–460l–11]; Safe Drinking Water Act [42 U.S.C. 300f–300j–9.]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Transportation Equity Act for the 21st Century (TEA–21) [23 U.S.C. 103(b)(6)(m), 133(b)(11)] (wetlands mitigation banking); Flood Disaster Protection Act of 1973 [42 U.S.C. 4001–4129].

8. Hazardous Materials: Comprehensive Environmental Response, Compensation, and Liability Act [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 [Pub. L. 99–499]; Resource Conservation and Recovery Act [42 U.S.C. 6901–6992(k)].

9. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

The projects subject to this notice are:

1. *SH 9 Iron Springs EA and FONSI.* Project Location: Just south of Frisco, CO. Project Reference Number: C0091–041. Project Overview: A 1.3-mile stretch of SH 9, between mileposts 93 and 95, will be realigned, rather than widened on the existing alignment. This will provide a four-lane roadway while removing a tight, compound curve (known as Leslie's Curve) and moving the highway away from Dillon Reservoir, a drinking water source. A portion of the old roadway alignment will be turned into a bike path. Project Purpose: The purpose is to improve transportation along SH 9 by decreasing travel time, improving safety, and supporting the transportation needs of local and regional travelers while minimizing impacts to the surrounding environment and communities between the towns of Frisco and Breckenridge. Signed NEPA Documents and Permits: EA signed on May 6, 2014 and FONSI on December 18, 2014. *https://www.codot.gov/projects/hwy9f2b/sh-9-iron-springs-alignment-environmental-assessment.*

2. *Federal Blvd., 7th to Howard EA and FONSI.* Project Location: Denver, CO. Project Reference Number: NHPP 2873–172. Project Overview: This project would widen Federal Boulevard to provide a third northbound lane and standard (11 foot) lane widths. Sidewalks will be brought up to Americans with Disabilities Act standards and existing crosswalks will be upgraded with new traffic and pedestrian signals. Project Purpose: The purpose of the project is to improve safety for all modes of travel (*e.g.,* personal vehicles, transit vehicles, and bicycles as well as foot traffic), improve traffic operations for all traffic modes, reduce existing and future northbound congestion, and enhance multi-modal connectivity. Signed NEPA Documents and Permits: EA signed on October 8, 2014 and FONSI on January 15, 2015. *http://www.denvergov.org/infrastructure/policyandplanning/currentprojects/federalboulevard/tabid/442758/default.aspx* and *https://www.codot.gov/projects/federalea7thtohoward.*

3. *US 50 West, Purcell Blvd. to Wills Blvd., and McCulloch Blvd. Intersection Improvements EA and FONSI.* Project Location: Pueblo, CO. Project Reference Number: STA 050A–022. Project Overview: Highway improvements include adding an additional 3.4-mile eastbound lane to US 50 between Purcell Blvd. and Wills Blvd. Intersection improvements include turn lanes, and deceleration and acceleration lanes. Project Purpose: The purpose is to reduce congestion and improve safety. Signed NEPA Documents and Permits: EA signed on June 3, 2014 and FONSI on September 15, 2014. *https://www.codot.gov/library/studies/us50ea.*

4. *US 24 West EA and FONSI.* Project Location: Colorado Springs, CO. Project Reference Number: NH 0242–040. Project Overview: The project encompasses a 4-mile segment of US 24 from Interstate 25 to west of the Manitou Avenue interchange. It includes additional lanes in approximately 1 mile of the project area, bridge replacements on US 24 and cross streets, replacing two intersections with interchanges, closing some access points including replacing one intersection with an overpass, improvements to sidewalks on the north-south cross streets at all intersections and interchanges, and extending the Midland Trail. Project Purpose: The purpose is to reduce congestion problems for travelers today and through the year 2035; improve mobility for local trips within the US 24 corridor and regional trips through the US 24 corridor; and improve connectivity to the multiple destinations accessible from the US 24 corridor. Signed NEPA Documents and Permits: EA signed on May 16, 2012 and FONSI on October 2, 2014. *https://www.codot.gov/projects/us24west.*

5. *US 287 at Lamar Reliever Route EA and FONSI.* Project Location: Lamar, CO. Project Reference Number: C2871–026. Project Overview: The project will relocate US 287 and US 50 from downtown Lamar to a new alignment, known as the reliever route, approximately one mile east of Lamar. The new highway will serve as an alternate route around downtown Lamar for non-stop regional truck and automobile traffic. Project Purpose: The purpose is to reduce conflicts between local and through-traffic, improve safety, and meet local, regional, and national travel demands on US 287 and US 50 through Lamar. Signed NEPA Documents and Permits: EA signed on August 15, 2013 and FONSI on November 10, 2014. *https://www.codot.gov/projects/us287lamar.*

6. *US 550/US 160 South Connection SEIS and ROD.* Project Location: Durango, CO. Project Reference Number: FC–NH(CX)162–2(048). Project Overview: The project will realign a 1.5-mile portion of US 550 to connect with an interchange on US 160 and widen the road to four lanes. The SEIS focused on this portion of the original 2006 US 160 Durango to Bayfield EIS project, and looked at both previous and new alternatives developed to reduce impacts to historic properties identified after the completion of the previous ROD. Project Purpose: The purpose is to increase travel efficiency/capacity to meet current and future needs, improve safety for the traveling public by reducing the number and severity of crashes, and control access for safety and mobility improvements. Original FEIS signed May 12, 2006, ROD signed November 7, 2006 (claims limitation notice issued May 14, 2007), Signed NEPA Documents and Permits for this notice: SFEIS signed July 2, 2012, Revised Section 4(f) Evaluation signed April 23, 2015, and supplemental ROD signed April 23, 2015. *https://www.codot.gov/projects/us550-at-160.*

7. *US 36 Corridor ROD #2.* Project Location: Between Denver and Boulder,

CO. Project Reference Number: NH 0361–070. Project Overview: The portion of the project included in ROD #2 includes replacing two bridges and widening two bridges. Project Purpose: The purpose of improvements in the US 36 corridor is to improve mobility along the US 36 corridor from I–25 in Adams County to Foothills Parkway/Table Mesa Drive in Boulder, and among intermediate destinations. FEIS and Final Section 4(f) Evaluation signed October 30, 2009, ROD #1 signed December 24, 2009, and Department of the Army Permit No. 200380602 (claims limitation notice issued April 23, 2012). Signed NEPA Documents and Permits for this notice: FEIS and Final Section 4(f) Evaluation signed October 30, 2009, and ROD #2 signed September 24, 2012. *https://www.codot.gov/projects/us36eis.*

8. *I–25 Valley Highway, Logan to US 6 FEIS, ROD #1 and ROD #2.* Project Location: Denver, CO. Project Reference Number: BR 0061–083. Project Overview: The project will provide improvements to: I–25 (the Valley Highway) from Logan Street to US 6; US 6 from I–25 to Federal Boulevard; and on adjacent portions of Santa Fe Drive and Kalamath Street in south central Denver. The improvements would correct geometric deficiencies, add capacity, improve safety, and replace deteriorating structures. Pedestrian/bicycle mobility across the I–25 corridor and access to transit facilities would also be improved. Project Purpose: The purpose is to improve connectivity between transportation modes, improve pedestrian and bicycle mobility across the project corridor, increase safety along and across the corridor for motorists, pedestrians, and bicyclists, and correct roadway deficiencies to provide a safer, more efficient, and more reliable transportation system. Signed NEPA Documents and Permits: FEIS signed November 6, 2006, ROD #1 signed July 5, 2007 and ROD #2 signed February 8, 2013. *https://www.codot.gov/library/studies/i-25-valley-highway-EIS.*

**Authority:** 23 U.S.C. 139(l)(1).

**John M. Cater,**

*Division Administrator, Lakewood, Colorado.*

[FR Doc. 2015–11641 Filed 5–14–15; 8:45 am]

BILLING CODE 4910–22–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0059]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel WATERBOUND; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 15, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0059. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel WATERBOUND is:

INTENDED COMMERCIAL USE OF VESSEL: ''This waiver will allow only one additional Uninspected Passenger Vessel to begin operations in the Honolulu area. The vessel will only operate part time with not more than 6 passengers. The intended use is sightseeing captained charters, sailing lessons, underwater robotic sightseeing and short term captained charters. I am currently a Ph.D. candidate at the University of Hawaii and will also use the vessel to demonstrate underwater robotics to university students. These activities will supplement my education and income while at UH.''

GEOGRAPHIC REGION: ''Hawaii''

The complete application is given in DOT docket MARAD–2015–0059 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 11, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–11841 Filed 5–14–15; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0060]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HULA GIRL; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime

Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 15, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0060. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel *HULA GIRL* is:

*Intended Commercial Use of Vessel:* ''To take 2–12 passengers out for short day excursion on Biscayne Bay.''

*Geographic Region:* ''Florida''.

The complete application is given in DOT docket MARAD–2015–0060 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

By Order of the Maritime Administrator.

Dated: May 11, 2015.

**Thomas M. Hudson,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–11839 Filed 5–14–15; 8:45 am]

**BILLING CODE 4910–81–P**

---

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. DOT–MARAD–2015–0056]**

### Request for Comments of a Previously Approved Information Collection: Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length To Obtain a Fishery Endorsement

**AGENCY:** Maritime Administration (MARAD), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on February 18, 2015 (80 FR 8755).

**DATES:** Comments must be submitted on or before June 15, 2015.

**FOR FURTHER INFORMATION CONTACT:** Michael C. Pucci, (202) 366–5167, Division of Maritime Programs, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

**SUPPLEMENTARY INFORMATION:**

*Title:* Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement.

*OMB Control Number:* 2133–0530.

*Type of Request:* Renewal of a Previously Approved Information Collection.

*Abstract:* In accordance with the American Fisheries Act of 1998, owners of vessels of 100 feet or greater who wish to obtain a fishery endorsement to the vessel's documentation are required to file with the Maritime Administration (MARAD) an Affidavit of United States Citizenship and other supporting documentation.

*Affected Public:* Vessel owners, charterers, mortgagees, mortgage trustees and managers of vessels of 100 feet or greater who seek a fishery endorsement for the vessel.

*Estimated Number of Respondents:* 500.

*Estimated Number of Responses:* 500.

*Annual Estimated Total Annual Burden Hours:* 2950.

**ADDRESSES:** Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

Dated: May 11, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Maritime Secretary, Office of Chief Council.*

[FR Doc. 2015–11834 Filed 5–14–15; 8:45 am]

**BILLING CODE 4910–81–P**

---

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0061]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ZUIMACO; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation,

as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 15, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0061. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel ZUIMACO is:

*Intended Commercial Use Of Vessel:* ''Sailing charters with an emphasis on customizing our clients needs and time schedule. Charters offered to any type of group; couples, friends, families and corporate retreats. A first class charter experience that strives on safety and focuses on allowing clients to see the natural beauty of their surroundings.''

*Geographic Region:* Florida, North Carolina, New York, Massachusetts, Maine, New Hampshire, California, Hawaii. The complete application is given in DOT docket MARAD–2015–0061 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

By Order of the Maritime Administrator.

Dated: May 11, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–11838 Filed 5–14–15; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0057]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SEA FOX; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 15, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0057. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel SEA FOX is:

*Intended Commercial Use of Vessel:* ''The vessel will operate in a very narrow corner of the market, short term (1 or 2 weeks) recreational charters for one or two families.''

*Geographic Region:* ''Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida'' The complete application is given in DOT docket MARAD–2015–0057 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

By Order of the Maritime Administrator.

Dated: May 11, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–11835 Filed 5–14–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015 0058]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LIMITLESS; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 15, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0058. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov*.

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel LIMITLESS is: *Intended Commercial Use of Vessel:* ''Carrying passengers for hire.'' *Geographic Region:* ''Florida, Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey'' The complete application is given in DOT docket MARAD–2015–0058 at *http://www.regulations.gov*. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: May 11, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–11836 Filed 5–14–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[Docket No. FD 35927]**

### Eighteen Thirty Group, LLC—Acquisition Exemption—Lines of CSX Transportation, Inc.

Eighteen Thirty Group, LLC (Eighteen Thirty), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire from CSX Transportation, Inc. (CSXT) approximately 5.4 miles of rail line in Allegany County, Md., consisting of: (1) Approximately 4.8 miles of CSXT's Georges Creek Subdivision between Barton, approximately milepost BAI 27.0, and Westernport, approximately milepost BAI 31.6; and (2) approximately 0.60 miles of CSXT's Thomas Subdivision, namely the two tracks running parallel to the Thomas mainline track between approximately milepost BAH 26.2 and approximately milepost BAH 26.8.

This transaction is related to a concurrently filed verified notice of exemption in *Georges Creek Railway—Operation Exemption—Lines of CSX Transportation, Inc.,* Docket No. FD 35928, in which Georges Creek Railway, LLC (GCK) seeks Board approval to operate over the lines being acquired by Eighteen Thirty.[1]

Eighteen Thirty certifies that: (1) Its projected annual revenues as a result of the transaction will not exceed $5 million and will not result in the creation of a Class II or Class I rail carrier; and (2) the Transaction Agreement between CSXT and Eighteen Thirty, which is dated April 10, 2015, does not contain an interchange commitment.

The transaction may be consummated on or after May 31, 2015, the effective date of the exemption.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 22, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35927, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Fritz R. Kahn, Fritz R. Kahn, P.C., 1919 M Street NW., 7th Floor, Washington, DC 20036.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: May 8, 2015.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

**Jeffrey Herzig,**

*Clearance Clerk.*

[FR Doc. 2015–11796 Filed 5–14–15; 8:45 am]

**BILLING CODE 4915–01–P**

[1] On May 5, 2015, Eighteen Thirty and GCK filed a joint amendment indicating that a milepost designation was incorrectly described in their respective notices of exemption. However, on May 6, 2015, they jointly submitted a letter asking that the Board disregard their amendment.

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[Docket No. FD 35772]**

### San Joaquin Valley Railroad Co.—Lease Amendment and Operation Exemption Including Interchange Commitment—BNSF Railway Company

San Joaquin Valley Railroad Co. (SJVR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to continue to lease from BNSF Railway Company (BNSF) and operate the Landco spur line between the Porterville Subdivision, MP 111+ 4029 feet, near Oil Junction, Cal., and milepost 113 + 3717 feet at or near Bakersfield, Cal., a distance of approximately 2.0 ± miles (the Leased Line).

SJVR states that it has entered into an amendment to extend the term of, and make other minor changes to, the lease, which originally was part of a broader agreement between SJVR's predecessor, Tulare Valley Railroad Company, and BNSF's predecessor, The Atchison, Topeka and Santa Fe Railway Company (ATSF). SJVR states that it will continue to be the operator of the Leased Line.

According to SJVR, the agreement between SJVR and BNSF contains an interchange commitment that affects interchange with carriers other than ATSF, now BNSF. In its verified notice of exemption, SJVR submits a map of the affected interchange points. As required under 49 CFR 1150.43(h)(1), SJVR also provided additional information regarding the interchange commitment.

SJVR has certified that its projected annual revenues as a result of this transaction will not result in its becoming a Class II or Class I rail carrier. However, SJVR's projected annual revenues following this transaction will exceed $5 million. Accordingly, SJVR is required by Board regulations to send notice of the transaction to the national offices of the labor unions with employees on the affected lines at least 60 days before this exemption is to become effective, to post a copy of the notice at the workplace of the employees on the affected lines, and to certify to the Board that it has done so. 49 CFR 1150.42(e).

SJVR, concurrently with its verified notice of exemption, filed a request for waiver of the 60-day advance labor notice requirement under 49 CFR 1150.42(e). In that request SJVR asserts that: (1) No employees of the transferring carrier, BNSF, will be affected by the lease and no employees of BNSF or its predecessor have worked on the Leased Line since 1992; (2) no SJVR employees will be affected by the lease and there will be no operational changes; and (3) posting notices on the Leased Line would be futile because no BNSF employees work on the Leased Line. SJVR's waiver request will be addressed in a separate decision.

SJVR states that it expects to consummate the transaction on the effective date of this exemption. The Board will establish in the decision on the waiver request the earliest date this transaction may be consummated.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 22, 2015.

An original and 10 copies of all pleadings, referring to Docket No. FD 35772, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Eric M. Hocky, Clark Hill PLC, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: May 12, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

**Jeffrey Herzig,**

*Clearance Clerk.*

[FR Doc. 2015–11781 Filed 5–14–15; 8:45 am]

**BILLING CODE 4915–01–P**

---

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[Docket No. FD 35928]**

### Georges Creek Railway, LLC—Operation Exemption—Lines of CSX Transportation, Inc.

Georges Creek Railway, LLC (GCK), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to operate approximately 5.4 miles of rail line currently owned by CSX Transportation, Inc. (CSXT) in Allegany County, Md., consisting of: (1) Approximately 4.8 miles of CSXT's Georges Creek Subdivision between Barton, approximately milepost BAI 27.0, and Westernport, approximately milepost BAI 31.6; and (2) approximately 0.60 miles of CSXT's Thomas Subdivision, namely the two tracks running parallel to the Thomas mainline track between approximately milepost BAH 26.2 and approximately milepost BAH 26.8.

This transaction is related to a concurrently filed verified notice of exemption in *Eighteen Thirty Group—Acquisition Exemption—Lines of CSX Transportation, Inc.,* Docket No. FD 35927, in which Eighteen Thirty Group, LLC (Eighteen Thirty) seeks Board approval to acquire the lines GCK wishes to operate.[1]

GCK certifies that: (1) Its projected annual revenues as a result of the transaction will not exceed $5 million and will not result in the creation of a Class II or Class I rail carrier; and (2) the Transaction Agreement between CSXT and Eighteen Thirty, which is dated April 10, 2015, does not contain an interchange commitment.

The transaction may be consummated on or after May 31, 2015, the effective date of the exemption.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 22, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35928, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Fritz R. Kahn, Fritz R. Kahn, P.C., 1919 M Street NW., 7th Floor, Washington, DC 20036.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: May 8, 2015.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

**Jeffrey Herzig,**

*Clearance Clerk.*

[FR Doc. 2015–11915 Filed 5–14–15; 8:45 am]

**BILLING CODE 4915–01–P**

---

[1] On May 5, 2015, Eighteen Thirty and GCK filed a joint amendment indicating that a milepost designation was incorrectly described in their respective notices of exemption. However, on May 6, 2015, they jointly submitted a letter asking that the Board disregard their amendment.

## DEPARTMENT OF THE TREASURY

### United States Mint

### Citizens Coinage Advisory Committee Membership Applications

**ACTION:** Request for Citizens Coinage Advisory Committee Membership Applications.

**SUMMARY:** Pursuant to United States Code, Title 31, section 5135 (b), the United States Mint is accepting applications for appointment to the Citizens Coinage Advisory Committee (CCAC) as a member representing the *interests of the general public* in the coinage of the United States. The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of 11 voting members appointed by the Secretary of the Treasury:

- One person specially qualified by virtue of his or her education, training, or experience as nationally or internationally recognized curator in the United States of a numismatic collection;
- One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;
- One person specially qualified by virtue of his or her education, training, or experience in American history;
- One person specially qualified by virtue of his or her education, training, or experience in numismatics;
- Three persons who can represent the interests of the general public in the coinage of the United States; and
- Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately five to seven times per year. The United States Mint is responsible for providing the necessary support, technical services, and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is interested in candidates who are recognized as having unique and valued talents or as an accomplished professional; have demonstrated experience, knowledge, interest or background in a variety of fields, including numismatics, art, education, working with youth, or American heritage and culture; have demonstrated interest and a commitment to actively participate in CCAC meetings and activities, and a demonstrated understanding of the role of the CCAC and the obligations of a Special Government Employee; possess demonstrated leadership skills in their fields of expertise or discipline; possess a demonstrated desire for public service; and have a history of honorable professional and personal conduct, as well as successful standing in their communities; and who are free of professional, political, or financial interests that could negatively affect their ability to provide impartial advice.

*Application Deadline:* Friday, June 19, 2015.

*Receipt of Applications:* Any member of the public wishing to be considered for participation on the CCAC should submit a resume and cover letter describing his or her reasons for seeking and qualifications for membership, by email to *info@ccac.gov,* by fax to 202–756–6525, or by mail to the United States Mint; 801 9th Street NW., Washington, DC 20220; Attn: Greg Weinman. Submissions must be postmarked no later than Friday, June 19, 2015.

*Notice Concerning Delivery of First-Class and Priority Mail:*

First-class mail to the United States Mint is put through an irradiation process to protect against biological contamination. Support materials put through this process may suffer irreversible damage. We encourage you to consider using alternate delivery services, especially when sending time-sensitive material.

**FOR FURTHER INFORMATION CONTACT:** William Norton, United States Mint Liaison to the CCAC; 801 9th Street NW., Washington, DC 20220, or call 202–354–7458.

Dated: May 11, 2015.

**Beverly Ortega Babers,**

*Chief Administrative Officer, United States Mint.*

[FR Doc. 2015–11786 Filed 5–14–15; 8:45 am]

BILLING CODE P

## DEPARTMENT OF THE TREASURY

### United States Mint

### Notification of Citizens Coinage Advisory Committee; Public Meeting

**SUMMARY:** Pursuant to United States Code, Title 31, section 5135(b)(8)(C), the United States Mint announces the Citizens Coinage Advisory Committee (CCAC) public meeting scheduled for June 16–17, 2015.

*Date:* June 16–17, 2015.

*Time:*

June 16, 9:30 a.m. to 4:00 p.m.
June 17, 9:30 a.m. to 11:30 a.m.

*Location:* Conference Room A, United States Mint, 801 9th Street NW., Washington, DC 20220.

*Subject:* Review and consideration of candidate designs for the National Park Service 100th Anniversary Commemorative Coin Program, the Foot Soldiers of the 1965 Selma to Montgomery Voting Rights March Congressional Gold Medal, the 65th Infantry Regiment (Borinqueneers) Congressional Gold Medal, and the First Spouse Gold Coin honoring Nancy Reagan.

*Interested persons should call the CCAC HOTLINE at (202) 354–7502 for the latest update on meeting time and room location.*

In accordance with 31 U.S.C. 5135, the CCAC:

- Advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals.
- Advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.

▪ Makes recommendations with respect to the mintage level for any commemorative coin recommended.

**FOR FURTHER INFORMATION CONTACT:** William Norton, United States Mint Liaison to the CCAC; 801 9th Street NW., Washington, DC 20220; or call 202–354–7200.

Any member of the public interested in submitting matters for the CCAC's consideration is invited to submit them by fax to the following number: 202–756–6525.

**Authority:** 31 U.S.C. 5135(b)(8)(C).

Dated: May 11, 2015.

**Beverly Ortega Babers,**

*Chief Administrative Officer, United States Mint.*

[FR Doc. 2015–12000 Filed 5–14–15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0823]**

## Expanded Access to Non-VA Care Through the Veterans Choice Program Activities: Under OMB Review

**AGENCY:** Veterans Health 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 Health Administration (VHA), 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 and includes the actual data collection instrument.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before June 15, 2015.

**ADDRESSES:** Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov*. Please refer to ''OMB Control No. 2900–0823 (Expanded Access to Non-VA Care through the Veterans Choice Program)'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

**FOR FURTHER INFORMATION CONTACT:** Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov*. Please refer to ''OMB Control No. 2900–0823 (Expanded Access to Non-VA Care through the Veterans Choice Program)'' in any correspondence.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Titles: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program.*

*OMB Control Number:* 2900–0823.

*Type of Review:* Extension.

*Abstract:* Section 17.1515 requires eligible veterans to notify VA whether the veteran elects to receive authorized non-VA care through the Veterans Choice Program, be placed on an electronic waiting list, or be scheduled for an appointment with a VA health care provider. Section 17.1515(b)(1) also allows eligible veterans to specify a particular non-VA entity or health care provider, if that entity or provider meets certain requirements.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 185,721 burden hours.

*Estimated Average Burden per Respondent:* 2 minutes.

*Frequency of Response:* 12.64 times per year.

*Estimated Number of Respondents:* 440,794 respondents.

*Titles: Health-Care Plan Information for the Veterans Choice Program.*

*OMB Control Number:* 2900–0823.

*Type of Review:* Extension.

*Abstract:* Section 17.1510(d) requires eligible veterans to submit to VA information about their health-care plan to participate in the Veterans Choice Program.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 88,159 burden hours.

*Estimated Average Burden per Respondent:* 10 minutes.

*Frequency of Response:* 1.2 times per year.

*Estimated Number of Respondents:* 440,794 respondents.

*Titles: Submission of Medical Record Information under the Veterans Choice Program.*

*OMB Control Number:* 2900–0823.

*Type of Review:* Extension.

*Abstract:* Participating eligible entities and providers are required to submit a copy of any medical record related to hospital care or medical services furnished under this Program to an eligible veteran.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 464,428 burden hours.

*Estimated Average Burden per Respondent:* 5 minutes.

*Frequency of Response:* 29.80 times per year.

*Estimated Number of Respondents:* 187,000 respondents.

*Titles: Submission of Information on Credentials and Licenses by Eligible Entities or Providers.*

*OMB Control Number:* 2900–0823.

*Type of Review:* Extension.

*Abstract:* Section 17.1530 requires eligible entities and providers to submit verification that the entity or provider maintains at least the same or similar credentials and licenses as those required of VA's health care providers, as determined by the Secretary.

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 at 80 FR 8950, February 19, 2015.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:* 15,583 burden hours.

*Estimated Average Burden per Respondent:* 5 minutes.

*Frequency of Response:* Once annually.

*Estimated Number of Respondents:* 187,000 respondents.

By direction of the Secretary:

**Crystal Rennie,**

*VA Clearance Officer, Department of Veterans Affairs.*

[FR Doc. 2015–11678 Filed 5–14–15; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0751]**

### Agency Information Collection (Supplier Perception Survey) Activities Under OMB Review

**AGENCY:** Office of Acquisition and Logistics, 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 Office of Operations, Security, and Preparedness, 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 June 15, 2015.

**ADDRESSES:** Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–00751'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

**FOR FURTHER INFORMATION CONTACT:** Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0751'' in any correspondence.

**SUPPLEMENTARY INFORMATION:**

*Title:* Supplier Perception Survey.

*OMB Control Number:* 2900–0751.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* The data collected will be used to improve the quality of services delivered to VA customers and to help develop key performance indicators in acquisition and logistics operations across VA enterprise.

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 at 80 FR 4336 on January 27, 2015.

*Affected Public:* Business or other for profit, and not-for-profit institutions.

*Estimated Annual Burden:* 750 hours.

*Estimated Average Burden per Respondent:* 30 minutes.

*Frequency of Response:* On Occassion.

*Estimated Number of Respondents:* 1500.

By direction of the Secretary.

**Crystal Rennie,**

*VA Clearance Officer, Department of Veterans Affairs.*

[FR Doc. 2015–11763 Filed 5–14–15; 8:45 am]

**BILLING CODE 8320–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

**[OMB Control No. 2900–0128]**

### Proposed Information Collection (Notice of Lapse—Government Life Insurance); Comment Request

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to this notice. This notice solicits comments on information needed to determine claimants' eligibility to reinstate lapsed Government Life Insurance policy.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before June 15, 2015.

**ADDRESSES:** Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0128'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

**FOR FURTHER INFORMATION CONTACT:** Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0128'' in any correspondence.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Titles:*

a. Notice of Lapse—Government Life Insurance, VA Form 29–389.

b. Application for Reinstatement, VA Form 29–389–1.

*OMB Control Number:* 2900–0128.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* VA Forms 29–389 and 29–389–1 are used to inform claimants that their government life insurance has lapsed or will lapse due to non payment of premiums. The claimant must complete the application to reinstate the insurance and to elect to pay the past due premiums. VA uses the data collected to determine the claimant's eligibility for reinstatement of such insurance.

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 at 80 FR 7701 on February 11, 2015.

*Affected Public:* Individuals or Households.

*Estimated Annual Burden:*

a. VA Form 29–389—3,399 hours.

b. VA Form 29–389–1—1,060 hours.

*Estimated Average Burden Per Respondent:*

a. VA Form 29–389—12 minutes.

b. VA Form 29–389–1—10 minutes.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:*

a. VA Form 29–389—16,993.

b. VA Form 29–389–1—6,359.

By direction of the Secretary.

**Crystal Rennie,**

*Department Clearance Officer, Department of Veterans Affairs.*

[FR Doc. 2015–11750 Filed 5–14–15; 8:45 am]

BILLING CODE 8320–01–P

# FEDERAL REGISTER

Vol. 80 Friday,

No. 94 May 15, 2015


Part II

## Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notice

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Mandatory Guidelines for Federal Workplace Drug Testing Programs

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services.

**SUMMARY:** The Department of Health and Human Services (''HHS'' or ''Department'') is proposing to establish scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

**DATES:** Submit comments on or before July 14, 2015.

**ADDRESSES:** In commenting, please refer to file code SAMHSA–2015–2. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow ''Submit a comment'' instructions.
- *By regular mail.* You may mail written comments to the following address ONLY: SAMHSA, Attention Division of Workplace Programs (DWP), 1 Choke Cherry Rd., Room 7–1045, Rockville, MD 20850. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: SAMHSA, Attention DWP, 1 Choke Cherry Rd., Room 7–1045, Rockville, MD 20850.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: SAMHSA, Attention DWP, 1 Choke Cherry Rd., Room 7–1045, Rockville, MD 20850. If you intend to deliver your comments to the Rockville address, call telephone number (240) 276–2600 in advance to schedule your arrival with one of our staff members. Because access to the interior of the SAMHSA building is not readily available to persons without federal government identification, commenters are encouraged to schedule their delivery or to leave comments with the security guard front desk located in the main lobby of the building. Comments erroneously mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:** Charles LoDico, M.S., DABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 1 Choke Cherry Road, Room 7–1045, Rockville, MD 20850, telephone (240) 276–2600, fax (240) 276–2610, or email at *charles.lodico@samhsa.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

### Executive Summary

This notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) will allow federal executive branch agencies to collect and test an oral fluid specimen as part of their drug testing programs. In addition, some agencies, such as the Department of Transportation, are required to follow these guidelines in developing drug testing programs for their regulated industries, whereas others, such as the Nuclear Regulatory Commission (NRC), use the guidelines as part of the regulatory basis for their federal drug testing programs. These proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.

These Guidelines provide flexibility for federal agency workplace drug testing programs to address testing needs and remove the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988. Federal agencies, MROs, and regulated industries using these Guidelines will continue to adhere to all other federal standards established for workplace drug testing programs. These proposed OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (URMG).

The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. These proposed OFMG establish standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs.

### Summary of the Major Provisions of the Proposed OFMG

The promulgation of the OFMG allows federal agencies to collect and test oral fluid specimens in their workplace drug testing programs. The collection process for oral fluids provides that the specimen collection will be under observation. The OFMG enable split specimen testing by requiring two specimens to be obtained from the donor, either concurrently or serially, using separate collection devices or a single collection device that can be split into two separate specimens. Unlike the urine Mandatory Guidelines for Federal Workplace Drug Testing Programs (UrMG), Instrumented Initial Test Facilities are not practical and will not be allowed due primarily to the limited sample volume of oral fluid collected from the donor. With the exception of 6-acetylmorphine, a metabolite of heroin, and benzoylecgonine, a metabolite of cocaine, the analytes detected in oral fluids are primarily parent compounds. The OFMG analyte cutoffs are much lower than those specified for urine in the UrMG because drug analyte concentrations in oral fluid are much lower than urine concentrations. The Department is proposing that all specimens be tested for either albumin or Immunoglobulin G (IgG) to determine whether the specimen is valid. In the event that an individual is unable to provide an oral fluid specimen, the federal agency may authorize the collection of a urine specimen. With the inclusion of oral fluid testing in federal agency workplace programs, medical review of drug test results will become more complex. The MRO must interpret laboratory reported drug test results for both urine and oral fluid specimens. To ensure that MROs remain up-to-date on drug testing issues, pharmacological and toxicological information, and federal agency rules and regulations, the OFMG require MRO requalification training and reexamination on a regular basis (*i.e.,* every five years).

### Costs and Benefits

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates the number of specimens tested annually for federal

agencies to be 150,000. HHS projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS certified laboratories currently testing non-regulated oral fluid specimens. Likewise, there will be minimal costs associated with changing initial testing to include methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) since current immunoassays can be adapted to test for these analytes. Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the National Laboratory Certification Program (NLCP). Laboratories choosing to apply for HHS certification will incur some administrative costs associated with adding the matrix and these analytes. However, laboratories performing urine and oral fluid drug testing have trained personnel, drug testing methods, and the infrastructure (*e.g.,* secured facilities, computer systems, and electronic reporting methods) in place. Estimated laboratory costs to complete and submit the application are $2,000, and estimated costs for the Department to process the application are $7,200. The initial certification process includes the requirement to demonstrate that their performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each applicant laboratory.

The following estimated costs are based on current costs for urine testing. Once oral fluid testing has been implemented, the cost per specimen for each initial test will range from $.06 to $0.20, due to reagent costs. Estimated costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported as positive, due to costs of sample preparation and analysis. Based on information from non-regulated workplace drug testing, approximately 1% of the submitted specimens is expected to be confirmed as positive for one or more of the following analytes: Oxycodone, oxymorphone, hydrocodone, and/or hydromorphone. Therefore, the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen. This would indicate that the total cost per specimen submitted for testing will increase by $0.11–$0.30. These costs for the laboratories or federal agencies choosing to use oral fluid in their drug testing programs will be incorporated into the overall testing cost for the federal agency submitting the specimen to the laboratory. Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators.

Based on current figures, approximately 7% (or 10,500) of the 150,000 specimens tested per year for HHS will be oral fluid, 180,000 oral fluid specimens for DOT, and 14,000 oral fluid specimens for NRC.

The federal agencies choosing to use oral fluid in their drug testing program may see many benefits including a reduction in time of the collection process; an observed collection method leading to reductions in rejected, invalid, substituted, and adulterated specimens; and an effective tool in post-accident testing identifying the parent or active drug. Productivity for federal agencies related to the drug free workplace program is expected to improve. For example, administrative data indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be between 1 and 3 hours. The Department believes the cost reduction as outlined in this Preamble will benefit the federal agencies and drug free workplace program.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public. Please note that all comments are posted in their entirety including personal or confidential business information that is included in a comment. SAMHSA will post all comments before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments. Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry RD., Rockville, MD, 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (240) 276–2600.

## Background

The Department of Health and Human Services (HHS) by the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564 has established the scientific and technical guidelines for federal workplace drug testing programs and established standards for certification of laboratories engaged in urine drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; [73 FR 75122]). The effective date of the Guidelines was

further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

**History and Proposed Changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs**

A focus of the HHS mission is to maintain the integrity and ensure the quality of federal drug-free workplace programs by a commitment to identify and mandate the use of the most accurate, reliable drug tests and methods available. To accomplish that goal, the Department has implemented an ongoing scientific review and program collaboration with federal regulators, researchers, the drug testing industry, and public and private sector employers. As the use of alternative specimens (other than urine), analytical test technologies, and types of commercial workplace drug testing products have increased over the past decade in the private sector, the Department, through SAMHSA's Drug Testing Advisory Board (DTAB), has responded by review of these new products and began a dedicated assessment of drug testing using alternative specimens, such as oral fluid (saliva), hair and sweat for possible application in federal agency workplace testing programs.

The following OFMG are the result of a directed Departmental assessment that began in 1997 with a 3-day scientific meeting of the DTAB. During that meeting, the DTAB members discussed drug testing using alternative specimens and the use of new and developing drug testing technologies that could be applicable to workplace drug testing programs. The DTAB meeting was open to the public. Following the initial meeting, members of the DTAB continued to review and analyze all available information on alternative specimens and testing technologies. These efforts resulted in identifying specific scientific, administrative, and procedural requirements necessary for a comprehensive federal workplace drug testing program that included alternative specimens and technologies.

For more than 15 years, the DTAB has continued to evaluate the science and information submitted by industry representatives on alternative specimens and technologies. The following section presents a chronology of meetings and events leading to these proposed Guidelines for the testing of oral fluid.

The first working draft of new guidelines, including the testing of alternative specimens, was presented at the June 2000 DTAB meeting. These initial, ''work-in-progress'' guidelines were placed on the SAMHSA Web site and the public was invited to submit supplemental information and informal comments to improve the draft and further SAMHSA's knowledge base. Twenty-eight separate comments were submitted. All comments were summarized, incorporated into the draft Guidelines and presented at the next DTAB meeting held in September 2000. At that DTAB meeting, a second working (revised) draft of the Guidelines was presented and, again, comments were requested from all interested parties. At the December 2000 DTAB meeting, the public comments submitted were used to prepare the third working draft of the Guidelines. Concurrently, SAMHSA organized three expert groups [Oral Fluid, Hair, and Sweat] that included members from science and industry.

To assess laboratory performance and utility of alternative specimen testing for use in federal workplace programs, the Department initiated a voluntary pilot proficiency testing (PT) program. This pilot program provides PT samples, developed and prepared at government expense, to a number of laboratories for testing. Participating laboratories used their routine procedures to test oral fluid, hair and sweat specimens and shared their PT results with SAMHSA. This pilot PT program was established for two reasons. The first was to determine if it was possible to prepare stable and accurate PT samples for the proposed specimen type that could be used in a laboratory certification program. Second, the PT results reported by the laboratories could be used to help establish criteria for the analysis of alternative specimens.

Based on data obtained from the pilot PT program, it appeared that valid PT samples could be prepared but refinement was needed. The results in the pilot PT program were encouraging, and both individual laboratory and collective performance improved over time; however, there remained some concern about the performance differences among the participating laboratories, and the applicability of some testing technologies used by the laboratories. By 2004, the working groups reached consensus and proposed standards for laboratory-based oral fluid, hair, and sweat testing procedures.

In April 2004, the Department issued a **Federal Register** notice [69 FR 19673] on the proposed inclusion of oral fluid, hair, and sweat specimens in federal workplace drug testing programs. Public comments and issues raised by federal agencies during the internal review of the proposed changes identified significant scientific, legal, and public policy concerns about the use of the alternative specimens. As a result of the internal review, the Department issued a Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs in November of 2008 [73 FR 71858] that concluded the scientific, technical, and legal information for the testing of alternative specimens (oral fluid, hair, and sweat) was insufficient to include these specimens in the federal programs at that time. However, the Department committed to monitoring developments in alternative specimen testing and has continued to do so since 2008.

The complexity of responses to the 2004 notice made it clear that if the Department were to subsequently authorize alternative specimens for the Mandatory Guidelines for Federal Workplace Drug Testing Programs, each specimen matrix would need a separate set of guidelines. Additionally, the Department proposed to stagger the timeline for the review and potential incorporation of alternative specimens, and to begin with oral fluid. The decision to begin with oral fluid was supported by fewer legal and policy concerns, and current peer-reviewed literature that existed with oral fluid.

Methods developed since 2004 offer enhanced analytical sensitivity and specificity for testing drugs in oral fluid. The scientific literature base for oral fluid testing and interpretation of results has grown substantially. Many non-regulated private sector organizations have incorporated oral fluid testing into their workplace programs. Also, during this period, SAMHSA funded a review of a Medical Review Officer (MRO) database of laboratory-reported results for urine and alternative specimens from both regulated and non-regulated workplaces. The study showed a dramatic increase in the use of oral fluid testing from 2003 to 2009.

At the open session of the January 2011 DTAB meeting, SAMHSA shared with DTAB and the public the most current information on the oral fluid specimen. During the meeting, experts made scientific presentations concerning oral fluid as a specimen for workplace drug testing, including: Physiological composition of oral fluid, tested drugs and cutoffs, collection devices, and best practices laboratory methodologies (initial and confirmatory testing). At approximately the same time, SAMHSA entered into an Interagency Agreement (IAA) with the Office of National Drug Control Policy (ONDCP) and received funding to update and expand the laboratory standards for federal forensic drug testing. The overall goal of this IAA was

to determine the state of the science for oral fluid collection, testing, and interpretation, to support the development of these proposed Guidelines to include the use of the oral fluid specimen. Additionally, the IAA required researching additional drugs of abuse that warranted addition to the existing urine specimen analyte panel. This included investigation of prescription drugs with high abuse and impairment potential.

Subsequent to the IAA and the January 2011 DTAB meeting, several working group meetings were held to discuss the oral fluid science and develop proposed Guidelines using oral fluid specimens. Working group members included federal partners, subject matter experts, industry leaders, stakeholders, and representatives from the National Laboratory Certification Program (NLCP).

In June 2011, SAMHSA solicited comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086]. The notice requested written opinions from the public and industry stakeholders regarding a variety of issues related to oral fluid testing, including potential analytes, cutoff concentrations, specimen validity, specimen collection, collection devices, testing methods and interpretation of analytical results. The RFI was an effort to give the public and industry stakeholders an additional opportunity to provide information and comments for consideration during the development of the draft Guidelines for oral fluid testing. The Department received 18 comments from drug testing laboratories, MROs, oral fluid collection device manufacturers, drug testing industry associations, and the public [available at *www.regulation.gov* (docket SAMHSA–2011–0001)]. All submitted comments were reviewed and were presented to the DTAB members for consideration during SAMHSA's continuing assessment of oral fluid as an alternative specimen.

At the July 2011 meeting of the DTAB, Board members voted unanimously for the following:

(1) Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs; and (2) DTAB recommends the inclusion of additional Schedule II prescription medications (*e.g.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

At the January 2012 DTAB meeting, the SAMHSA Administrator received the DTAB recommendations from the July 2011 meeting.

The DTAB recommendations, the results from the SAMHSA-funded PT program, and the private sector experience have led the Department to conclude that oral fluid should be included in the federal program as an alternative specimen.

**Rationale for the Inclusion of Oral Fluid in the Mandatory Guidelines for Federal Workplace Drug Testing Programs**

The scientific basis for use of oral fluid as an alternative specimen for drug testing has been broadly established.[1–12] Corresponding developments have proceeded in analytical technologies that provide the needed sensitivity and accuracy for testing oral fluid specimens.[13–28]

Oral fluid and urine test results have been shown to be substantially similar, and oral fluid may have some inherent advantages as a drug test specimen. Oral fluid collection will occur under observation, which should substantially lessen the risk of specimen substitution and adulteration and, unlike direct observed urine collections, the collector need not be the same gender as the donor.

*What is oral fluid?*

Oral fluid is the physiological fluid that can be collected from the oral cavity of the mouth. Oral fluid is comprised primarily of saliva produced by the submandibular, sublingual, and parotid glands.[29] Other sources that contribute to the composition of oral fluid are minor salivary glands, gingival crevicular fluid (fluid from between the gums and teeth), cellular debris, bacteria, and food residues.[30] The major constituent of oral fluid is water. Other components include electrolytes such as potassium, sodium, chloride, bicarbonates and phosphates, and organic substances such as enzymes, immunoglobulins, and mucins.[31] The composition of oral fluid is dynamic and varies with the rate of saliva production (flow rate). The pH of saliva is generally acidic, but may range from 6.0 to 7.8, depending upon the rate of saliva flow. As saliva flow increases, levels of bicarbonate increase, thus increasing pH.[32] The volume of saliva produced by individuals varies considerably from approximately 500 to 1500 mL per day. The total volume of oral fluid in the mouth after swallowing averages about 0.9 mL for adult males and 0.8 mL for adult females.[33]

*What is the mechanism of drug disposition in oral fluid?*

Drugs enter oral fluid primarily by diffusion from blood and from active drug use by oral, transmucosal, smoked, inhaled, and insufflated routes. Oral cavity tissues have a rich blood supply. The movement of drugs from blood (plasma) to oral fluid depends upon certain physicochemical properties of the drug. The primary restricting factors are drug lipophilicity, degree of ionization, and the degree of drug binding with plasma proteins.[34] Lipid-soluble molecules pass through cell membranes more efficiently than those that are more water soluble (*e.g.,* drug metabolites). Consequently, parent (unmetabolized) drug is frequently the predominant analyte identified in oral fluid. Biological membranes are not permeable to the drug fraction that is bound to plasma proteins or to drug that is in the ionized state; hence only free, non-protein bound and non-ionized drug in plasma can diffuse into saliva. Consequently, oral fluid drug concentrations are closely related to the free, unbound drug in blood (plasma). For those drugs that are weak bases (*e.g.,* cocaine, opioids, amphetamines, and phencyclidine), concentrations in oral fluid frequently are higher than plasma concentrations as a result of ''ion-trapping'' due to oral fluid's higher acidity relative to plasma. Despite these restrictions, drug transfer from blood to oral fluid is a rapid process as demonstrated by consistent positive tests for drug in oral fluid two to five minutes following an intravenous injection of heroin [35] or cocaine.[36] The correlations of drug concentrations in oral fluid to those in plasma vary substantially from drug to drug.[4]

Deposition of drugs in oral fluid can also occur from external sources. For example, drugs in food sources (*e.g.,* morphine in poppy seeds) are a potential source of contamination.[37] Drug residues can initially be deposited in high concentration in oral fluid during active drug administration by oral, transmucosal, smoked, inhaled, and insufflated routes.[1 35 36] Generally, deposited drug residues disappear fairly rapidly because of inherent self-cleansing mechanisms of the oral cavity (*e.g.,* saliva production and subsequent swallowing).

Detection times are influenced by many pharmacological and chemical factors associated with the drug, dose, route of administration, frequency of drug use, biology of the individual, specimen type, and the sensitivity of the detection system. In general, detection times in oral fluid are somewhat shorter

than observed for urine. In oral fluid, drugs of abuse are detected for 5 to 48 hours after use, whereas in urine, the detection time is 1.5 to 4 days or longer with chronic drug use.[11 38] However, as described below, positivity rates for oral fluid reported for non-regulated workplace testing are the same as or higher than urine positivity rates. These rates demonstrate the equivalency of these specimen types in identifying drug use, despite differences in drug detection times.

*How do testing positivity rates compare between oral fluid and urine?*

In the absence of paired specimen collections (*i.e.,* urine and oral fluid from the same donor) in workplaces, the positivity rates of urine and oral fluid tests can be used to infer the relative effectiveness of these two specimen types.

The workplace positivity rates for drugs in oral fluid appear to be generally comparable to corresponding rates reported for urine. The 2013 Drug Testing Index (DTI) by Quest Diagnostics for drugs in the general workforce indicated positivity rates for oral fluid as 0.59 percent amphetamines (combined percentages of amphetamine and methamphetamine), 0.31 percent cocaine, 4.0 percent marijuana, 0.88 percent opiates, and 0.02 percent PCP and, for urine, as 0.87 percent amphetamines, 0.21 percent cocaine, 2.0 percent marijuana, 0.44 percent opiates and 0.01 percent PCP.[39] The overall drug positivity rate for oral fluid was 5.5 percent compared to 4.1 percent for urine. An earlier study of 77,218 oral fluid specimens reported similar trends in the positive prevalence rates compared to the DTI for urine specimens collected during the same period.[40] In that study, the overall combined positivity rate for oral fluid was 5.06 percent compared to 4.46 percent for urine. Both sets of data compared positivity rates in two separate workplace populations over a comparable time period. The higher positivity rates for oral fluid are most likely due to the fact that oral fluid collections are performed under observation, reducing the ability of donors to substitute or adulterate the specimen.

Only limited studies have compared positivity rates from ''paired'' specimen collections in the same population. A clinical study involving compliance monitoring of pain patients compared test results for oral fluid to urine specimens collected in ''near simultaneous fashion.'' [41] The specimens were analyzed for 42 drugs and/or metabolites by mass spectrometric procedures. The authors evaluated two subsets of data related to federal workplace drug testing: 263 comparisons of currently tested drugs (*i.e.,* morphine, codeine, cannabinoids, cocaine, amphetamine, and methamphetamine) and 491 comparisons that included these drugs plus hydrocodone and oxycodone. For the first data set, 92.4 percent of the oral fluid and urine specimens had the same results (*i.e.,* positive/positive or negative/negative). For the second data set (which included hydrocodone and oxycodone test results), 89.2 percent of the specimens had the same results (*i.e.,* positive/positive or negative/negative). Statistically, both data sets exhibited substantial agreement in results between oral fluid and urine. The overall result discordance for the current drugs was 5.5%, of which 2.5% were positive in oral fluid and negative in urine, and 3% were negative in oral fluid and positive in urine. For hydrocodone, 9 (7.9%) analyte results were positive in oral fluid and negative in urine, while only 1 (0.09%) analyte result was negative in oral fluid and positive in urine. For oxycodone, 9 (7.9%) analyte results were positive in oral fluid and negative in urine, and 14 (12.3%) analyte results were negative in oral fluid and positive in urine. Differences in time courses of drugs and metabolites in these matrices may explain the discordant results.

Another study compared positivity rates from paired specimens from 45 subjects (164 paired sets of specimens) of treatment patients stabilized on either methadone or buprenorphine.[42] Aside from methadone or buprenorphine, 595 (21.1 percent) drug analytes were positive and 1948 (69.0 percent) were negative for both specimens for an overall agreement of 90 percent. There were 82 (2.9 percent) analyte results that were positive in oral fluid and negative in urine, and 199 (7.0 percent) that were negative in oral fluid and positive in urine, for an overall disagreement of 10 percent. Morphine was found more often in urine (n=66) than in oral fluid (n=48), whereas 6-acetylmorphine was found more often in oral fluid (n=48) than in urine (n=20). Amphetamine and methamphetamine were found slightly more often in oral fluid than in urine. Benzodiazepines and cannabis were found more frequently in urine.

Several studies have been reported comparing oral fluid testing to urinalysis for individuals under criminal justice supervision.[43–45] In one study, the agreement rates between an oral fluid initial test result and confirmed urine test for 223 probationers ranged from 90 to 99 percent.[44] The lowest agreement rate (90 percent) was for marijuana, with 20 of the 23 discordant specimens negative by oral fluid and positive by urine testing. Two studies reported almost identical rates of recent cocaine and opiate use from either type of test, but oral fluid was less effective in detection of marijuana users than urinalysis.[43 45]

*How were analytes and cutoffs selected?*

The selection of analytes for testing was based on known drug disposition patterns in oral fluid. Some drug disposition patterns in oral fluid are similar to urine and others differ in relative amounts of parent drug versus metabolite and in type of metabolite. The mechanisms of drug excretion in oral fluid are somewhat different than in urine. In some cases, direct deposition of parent drug in oral fluid may occur by oral, snorted (insufflated), transmucosal, inhaled, and smoked routes of administration. When this occurs, the metabolites generally appear later in oral fluid. For some drugs (*e.g.,* cocaine and heroin), it appears that direct hydrolysis may also occur.[35 36] The primary means of entry into oral fluid for most drugs (and metabolites) is by passive diffusion of un-ionized, non-protein bound fraction of drug from plasma. Diffusion into oral fluid occurs more readily for lipophilic drugs than for water-soluble metabolites. As a result of these mechanisms, parent (unmetabolized) drug is frequently the primary analyte present in oral fluid. Urinary excretion occurs more readily for water-soluble metabolites; lipid-soluble drugs are frequently re-absorbed back into blood during urinary excretion.

The route of administration influences the time course of both drug and metabolites in oral fluid.[46] Orally administered drugs generally undergo some degree of metabolism in the gastrointestinal tract and liver prior to entering the bloodstream, whereas injected and smoked drugs are absorbed primarily intact without metabolite formation. Once drugs (and metabolites) enter the bloodstream, they rapidly diffuse into oral fluid by excretion from highly blood-perfused salivary glands. Consequently, oral fluid tests generally are positive for parent drug as soon as the drug is absorbed into the body. Additional information on analyte selection for each drug is provided below in Subpart C, Oral Fluid Specimen Tests. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation.

*Will there be specimen validity tests for oral fluid?*

In regard to specimen validity testing for oral fluid, the Department considered measuring various oral fluid components (*e.g.,* amylase, albumin, and immunoglobulins such as IgG). Given that collection of oral fluid specimens will occur under observation, the Department did not find sufficient justification for extensive validity testing to identify attempts to adulterate or substitute specimens. However, both IgG and albumin in oral fluid are currently being used in the industry to identify specimen collections in which insufficient oral fluid was collected. The Department is proposing that all oral fluid specimens be tested for one of these components, but specifically requests public comment on requiring these tests.

Review of the literature for concentrations of albumin in oral fluid found that healthy subjects were characterized by concentrations ranging from 2.6–23.8 mg/dL [47] and in patients with cancer and renal failure,[48 49] the albumin concentrations ranged from 1.0–12.2 mg/dL. These data support using the industry cutoff of 0.6 mg/dL as a decision point for albumin in oral fluid.

Literature concerning the concentrations of IgG in oral fluid found that only predentate babies exhibited IgG concentrations below 1 mg/L.[50] Adults with and without teeth had a concentration mean of 19 mg/L. The mean for elderly adults with teeth was 24 mg/L and the mean for edentate elderly adults was 5.2 mg/L. Young healthy adults under various exercise routines had IgG concentrations means ranging from 5 mg/L to greater than 40 mg/L.[51] These data support using the industry cutoff of 0.5 mg/L as a decision point for IgG in oral fluid.

To avoid prohibiting other oral fluid specimen validity tests that may become available, the Department is also authorizing additional specimen validity testing as described in Section 3.1.d and Section 3.5.

The Department maintains that allowing tests for biomarkers other than albumin and IgG can be useful. The draft OFMG requirements are analogous to the current urine drug testing requirements in that laboratories *must* perform specified specimen validity tests on all specimens and *may* perform additional specimen validity tests for other measurands. The Department does not want to limit the testing to albumin and IgG, because other tests or biomarkers may be identified for use. The tests must be forensically acceptable and scientifically sound. Because OF specimen collections are observed and because oral fluid may be collected using a device in which the specimen is diluted by a buffer, a laboratory cannot definitively state that a specimen has been substituted. (The collector or MRO may report a refusal to test as described in Section 1.7 of the OFMG.) As noted in Section 13.5 of the OFMG, when an OF test is reported as Invalid and the donor has no legitimate explanation for the Invalid result, the MRO directs the agency to collect another specimen. The agency may decide the type of specimen for the recollection.

*How will oral fluid be collected?*

The Department recognizes that methods for collection of oral fluid specimens vary by manufacturers of devices and that new, innovative methods may be developed that offer improvements over existing methods. Two basic types of collection devices currently exist: One is designed to collect undiluted (neat) oral fluid by expectoration; the second type makes use of an absorbent pad that is inserted into the oral cavity for specimen collection and then placed in a tube containing a diluent. The Department is recommending that all collection devices maintain the integrity of the specimen during collection, storage and transport to the laboratory for testing. All devices must have an indicator that demonstrates the adequacy of the volume of collected specimen; have a sealable, non-leaking container; and have components that ensure pre-analytical drug and drug metabolite stability; and the device components must not substantially affect the composition of drugs and drug metabolites in the oral fluid specimen.

*What are the performance requirements for a collection device?*

The Department proposes that a collection device should collect either a minimum of 1 mL of undiluted (neat) oral fluid or, for those collection devices containing a diluent (or other component, process, or method that modifies the volume of the specimen), that the volume of oral fluid collected should be within 0.1 mL of the target volume and the volume of diluent in the device should be within 0.05 mL of the diluent target volume. The Department recommends that the device maintain stability of drug and/or drug metabolite in the oral fluid specimen allowing ≥90 percent recovery for one week at room temperature (18–25 °C). To ensure that collection device components do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen, the Department recommends that the device performance characteristics are such that there is ≥90 percent recovery (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff concentration. The established upper range is to minimize a collection device concentrating the specimen on the collection pad and/or the device. Numerous studies of stability and recovery of drugs from commercial oral fluid collection devices indicate wide variability in performance characteristics.[52–57] The recommended limits of ≥90 percent but no more than 120 percent recovery ensure concentration accuracy (within experimental limits), prevent potential concentration of drug and/or metabolite by the device, and ensure consistency in specimen collections using different collection devices.

The Department notes that these collection devices are subject to clearance by the FDA. The Department requests comments on whether HHS should publish a list of FDA-cleared oral fluid collection devices.

*What are the collection procedures?*

The Department is recommending that a split specimen be collected either (1) as two specimens collected simultaneously or serially with two separate collection devices, or (2) collected with a collection device that subdivides the specimen into two separate collection tubes. If collected serially, collection of the second specimen must begin within two minutes after the completion of the first collection. The Department believes this allows sufficient time for the collector to begin the second specimen collection in a timely manner, to minimize differences in oral fluid collected using two separate collection devices. Oral fluid test results for delta-9-tetrahydrocannabinol (THC) in simultaneously collected specimens with an absorbent pad have been reported to be highly correlated.[58]

In addition, the Omnibus Transportation Employee Testing Act (OTETA), which governs the DOT-regulated testing programs as well as the Federal Aviation Administration's federal employee testing program, requires that collected specimens must be able to be subdivided, to allow for additional testing upon request of the employee.

Therefore, the Department requests comments on whether serial or simultaneous collection using two collection devices constitutes a split

collection, and recommendations for any other oral fluid collection processes that enable subdividing the collected specimen.

*What new drugs are being included?*

Since the late 1980's, multiple recommendations have been made that additional drugs be considered for inclusion in workplace drug testing. These recommendations resulted in the Ecstasy-related drugs—methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)—being included for testing in 2008. The 2012 National Survey on Drug Use and Health (NSDUH) indicated that past month illicit drug use of psychotherapeutics was second only to marijuana in prevalence among persons aged 12 or older in the United States. Prescription psychotherapeutics include pain relievers, tranquilizers, stimulants, and sedatives.[59] The abuse of narcotic pain relievers has become a serious and growing public health concern.

Like heroin, many are derived from opium, but are synthetic analogs. Oxycodone and hydrocodone top the list of narcotic pain relievers causing visits to hospital emergency departments due to non-medical use,[60] and are among the top 10 drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories, ranking second and third of prescription drugs on the list.[61] Because of the prevalence of their abuse, hydrocodone and oxycodone have been included in these proposed OFMG.

Hydrocodone is metabolized in the body to hydromorphone and excreted in biological fluids.[62] Hydromorphone is also available commercially as an analgesic, is more potent than hydrocodone, and exhibits significant abuse liability. Oxycodone is metabolized in the body to oxymorphone and excreted in biological fluids.[63] Oxymorphone is also available commercially as an analgesic, is more potent than oxycodone, and exhibits significant abuse liability. For these reasons, hydromorphone and oxymorphone are also included in these proposed OFMG.

**Provisions for the Administration of the National Laboratory Certification Program (NLCP)**

In accordance with the current practice, an HHS contractor will perform certain functions on behalf of the Department. These functions include maintaining laboratory inspection and PT programs that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Department regarding certification or suspension/revocation of laboratories' certification. It is important to note that, although a contractor gathers and evaluates information provided by the inspectors or laboratories, all final decisions regarding laboratory certification, suspension or revocation of certification are made by the Secretary.

In addition, a contractor has historically collected certain fees from the laboratories for services related to the certification process, specifically for laboratory application and inspection and PT activities for laboratories applying to become HHS-certified, and for inspection and PT activities for laboratories maintaining HHS certification. All fees collected by a contractor are applied to its costs under the contract.

This same process, used since the inception of the laboratory certification program, will also be used by an HHS contractor to collect similar fees from laboratories that seek, achieve, and continue HHS certification to test oral fluid. The Department also contributes funds to this contract for purposes not directly related to laboratory certification activities, such as evaluating technologies and instruments and providing an assessment of their potential applicability to workplace drug testing programs.

**Organization of Proposed Guidelines**

This preamble describes the differences between the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens (UrMG) and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens (OFMG), and provides the rationale for the differences. In addition, the Preamble presents a number of the remaining issues raised during the development of Guidelines for oral fluid drug testing. The issues are organized and presented first in summary as they appear in the text of the proposed OFMG and later as issues of special interest for which the Department is seeking specific public comment.

**Subpart A—Applicability**

Sections 1.1, 1.2, 1.3, and 1.4 contain the same policies as described in the current UrMG with regard to who is covered by the Guidelines, who is responsible for the development and implementation of the Guidelines, how a federal agency requests a change from these Guidelines and how these Guidelines are revised.

In section 1.5, where terms are defined, the Department proposes to add terms that apply specifically to oral fluid (*e.g.,* collection device, oral fluid specimen).

Sections 1.6, 1.7, and 1.8 contain the same policies as described in the current UrMG with regard to what an agency is required to do to protect employee records, the conditions that constitute refusal to take a federally regulated drug test, and the consequences of a refusal to take a federally regulated drug test.

**Subpart B—Oral Fluid Specimen**

In section 2.1, the Department proposes to expand the drug-testing program for federal agencies to permit the use of oral fluid specimens. There is no requirement for federal agencies to use oral fluid as part of their program. A federal agency may choose to use urine, oral fluid, or both specimen types in their drug testing program. However, any agency choosing to use oral fluid is required to follow the OFMG. For example, an agency program can randomly assign individuals to either urine or OF testing, for random or pre-employment testing. This would not only help reduce subversion, but would allow comparison of urine and OF testing outcomes for planning purposes.

Section 2.2 describes the circumstances under which an oral fluid specimen may be collected. The Department has included this section to ensure that the circumstances described are consistent with the reasons for collecting a specimen as listed on the Federal Custody and Control Form (Federal CCF). The Department will review comments on the reasons that are appropriate for oral fluid testing.

Section 2.3 describes how each oral fluid specimen is collected for testing. The Department is seeking comment on whether the described procedures are consistent with the established requirement for all specimens to be collected as a split specimen and recommendations for other processes that enable subdividing the collected specimen.

Section 2.4 establishes a known volume that must be collected for each specimen.

Section 2.5 describes how a split oral fluid specimen is collected.

Section 2.6 clarifies that all entities and individuals identified in Section 1.1 of these Guidelines are prohibited from

releasing specimens collected under the federal workplace drug testing program to any individual or entity unless expressly authorized by these Guidelines or in accordance with applicable federal law.

While these Guidelines do not authorize the release of specimens, or portions thereof, to federal employees, the Guidelines afford employees a variety of protections that ensure the identity, security and integrity of their specimens from the time of collection through final disposition of the specimen. There are also procedures that allow federal employees to request the retesting of their specimen (for drugs or adulteration) at a different certified laboratory. Furthermore, the Guidelines grant federal employees access to a wide variety of information and records related to the testing of their specimens, including a documentation package that includes, among other items, a copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, and any memoranda generated by the laboratory.

Therefore, the Guidelines offer federal employees and federal agencies transparent and definitive evidence of a specimen's identity, security, control and chain of custody. However, the Guidelines do not entitle employees access to the specimen itself or to a portion thereof. The reason for this prohibition is that specimens collected under the Guidelines are uniquely designed for the purpose of drug and validity testing only. They are not designed for other purposes such as deoxyribonucleic acid (DNA) testing. Furthermore, conducting additional testing outside the parameters of the Guidelines would not guarantee incorporation of the safeguards, quality control protocols, and the exacting scientific standards developed under the Guidelines to ensure the security, reliability and accuracy of the drug testing process.

**Subpart C—Oral Fluid Specimen Tests**

Section 3.1 describes the tests to be performed on each oral fluid specimen. This is the same policy that is in the current UrMG regarding which drug tests must be performed on a specimen. A federal agency is required to test all specimens for marijuana and cocaine and is authorized to also test specimens for opiates, amphetamines, and phencyclidine. The Department realizes that most federal agencies typically test for all five drug classes authorized by the existing Guidelines, but has not made this a mandatory requirement, and will continue to rely on the individual agencies and departments to determine their testing needs above the required minimum. The Department included requirements for federal agencies to test all oral fluid specimens for either albumin or IgG to determine specimen validity, but specifically requests public comment on requiring these tests.

The policy in section 3.2 is the same as that for urine testing. Any federal agency that wishes to routinely test its specimens for any drug not included in the Guidelines must obtain approval from the Department before expanding its program. A specimen may be tested for any drug listed in Schedule I or II of the Controlled Substances Act when there is reasonable suspicion/cause to believe that a donor may have used a drug not included in these Guidelines. When reasonable suspicion/cause exists to test for another drug, the federal agency must document the possibility that the use of another drug exists, attach the documentation to the original Federal CCF, and ensure that the HHS-certified laboratory has the capability to test for the additional drug. The HHS-certified laboratory performing such additional testing must validate the test methods and meet the quality control requirements as described in the Guidelines for the other drug analyses.

Section 3.3 states that specimens must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Additional explanation is provided above, in comments for Section 2.6.

Section 3.4 lists the proposed analytes and cutoff concentrations for undiluted (neat) oral fluid. The table in Section 3.4 specifies both initial and confirmatory cutoff concentrations for each drug test analyte. Footnote 2 of the table addresses requirements that differ for initial tests using immunoassay-based technology and those using an ''alternate'' technology. Over the last 5 years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy. The proposed Guidelines allow the use of alternate technologies provided that the laboratory validates the method in accordance with Section 11 and demonstrates acceptable performance in the PT program.

Considerable research and discussion were conducted regarding the complex issues surrounding the specification of each cutoff concentration. The Department solicited input from laboratories, reagent and device manufacturers, subject matter experts, and the Food and Drug Administration (FDA). The cutoff concentrations are the outcome of the lengthy discussion process and represent the best approach currently available. The proposed analytes follow: *Marijuana (Cannabis).*

The Department is proposing to test for delta-9-tetrahydrocannabinol (THC) using a 4 ng/mL cutoff concentration for the initial test. For the confirmatory test, the Department is proposing to test for THC using a 2 ng/mL cutoff concentration.

Marijuana (cannabis) continues to be the most prevalent drug of abuse in the U.S. THC is the primary psychoactive ingredient of marijuana and is rapidly transferred from the lungs to blood during smoking.[64] THC is distributed by the blood and absorbed rapidly by body tissues. Apparently, very little unchanged THC is excreted in oral fluid as demonstrated by investigations with intravenously administered THC[65] or orally administered THC (dronabinol).[66] The major source of THC in oral fluid occurs from deposition in the mouth during smoking or oral use.[65] THC appears at its highest concentration in oral fluid immediately after smoking marijuana.[58 67 68 69] Initial high concentrations of THC in oral fluid decline rapidly within the first 30 minutes after use and thereafter decline over time in a manner similar to that observed for THC in plasma[68] and serum.[70] It has been suggested that the similarity in oral fluid and plasma concentrations can be attributed to a physiological link involving transmucosal THC absorption from oral fluid into blood.[1] One study reported significant correlations of oral fluid THC concentrations with subjective intoxication and with heart rate elevation.[71]

Positive prevalence rates for THC in oral fluid specimens collected from workplace drug testing programs appear to be comparable or greater than 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA) rates for urine drug testing in the general workforce. A 2002 study of 77,218 oral fluid specimens revealed a positive prevalence of 3.22 percent compared to a 3.17 percent positivity rate for more than 5,200,000 urine specimens collected during the same period.[40] The 2012 Drug Testing Index by Quest Diagnostics for marijuana positivity in the general workforce for oral fluid was 4.0 percent and for urine was 2.0 percent.[39]

Once absorbed and distributed to tissues, THC is ultimately transformed by oxidative metabolic enzymes to THCA. Further metabolism of THCA leads to formation of a glucuronide

metabolite (conjugated metabolite). Both free (unconjugated) THCA [72–74] and conjugated THCA [75] are excreted in oral fluid in low concentrations (picograms per milliliter). In a study of one frequent marijuana smoker,[75] concentrations of THC were highest immediately following smoking and declined thereafter. In that study, THC concentrations in oral fluid specimens collected during three different smoking occasions ranged from 0 to 93 ng/mL; free THCA concentrations ranged from 0.027 to 0.085 ng/mL and total (conjugated and free) THCA concentrations ranged from 0.033 to 0.314 ng/mL. The ratio of conjugated THCA to free THCA ranged from 0.5 to 3.64. Predominantly, there was approximately twice as much conjugated THCA as free THCA in oral fluid specimens, indicating the need for hydrolysis prior to confirmatory analysis to convert conjugated THCA to free THCA, enabling analysis for total THCA. Urine testing programs currently use hydrolysis and test for total THCA, and the analytical procedures for oral fluid are similar to those in practice for urine.

In contrast to urine, there is a paucity of scientific data on the time course of excretion or the detection window of THC, THCA, and conjugated THCA in oral fluid following marijuana use.[1] This is especially true for occasional users. Studies of daily marijuana smokers indicate that THC is detectable for up to two days, but THCA continues to be excreted in oral fluid during abstinence for several weeks in daily users.[76] As noted earlier, the mechanisms of drug excretion in oral fluid are somewhat different than in urine. Because oral fluid tests generally are positive for parent drug as soon as the drug is administered, the Department, for oral fluid testing, is considering testing and confirming for THC. THC is reliably present in oral fluid immediately after smoked cannabis administration and remains detectable for 24–30 hours or longer, whereas THCA may or may not be present. The risks of passive smoke exposure have been assessed. To date, studies have indicated that transient amounts of THC may be present in oral fluid for a few hours (1–3), and no THCA is detected in oral fluid but is detected in blood. The detection of traces of THC occurred only under conditions of extreme tolerated exposure. Unknowing or transient exposure to marijuana smoke does not appear likely to produce a positive THC test in oral fluid. The Department seeks comment on whether THCA is suitable for inclusion as a reliable test analyte for detection of marijuana use.

The proposed initial test cutoff for THC (4 ng/mL) and confirmatory test cutoff for THC (2 ng/mL) are the same as those proposed in the 2004 Guidelines. The detection time for THC in oral fluid appears to be shorter than the detection time for THCA in urine;[58 67 76 77 78 79] consequently, a lower initial test cutoff concentration would enhance detection rates of marijuana use. For this reason, the Department is interested in receiving comments on lowering the cutoff concentration for delta-9-tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff concentration and to 1 ng/mL for the confirmatory cutoff concentration. Lowering the initial and confirmatory test cutoff concentrations would lengthen the detection window (*i.e.,* the number of hours after a drug is ingested by an individual that the concentration of the drug or drug metabolite in oral fluid will likely be at or above the cutoff concentration). Lower cutoff concentrations will increase the number of specimens that are identified as containing THC and, thereby, will increase the deterrent effect of the program and improve identification of employees using this illicit substance.

The Department had considered proposing to test for THCA (*i.e.,* ''total'' amount following hydrolysis, as described above) using a 0.050 ng/mL cutoff concentration for confirmation to extend the window of detection. However, the Department is concerned over the utility of confirming for this analyte as well as the ability of laboratories to reliably implement this test for routine analyses, based on the reasons provided below

Currently, few laboratories perform confirmatory testing for THCA in oral fluid testing. Thus, there is limited data on the positivity rates for these analytes in a workplace population. In a study of 143 specimens positive by immunoassay using the proposed 4 ng/mL initial test cutoff,[74] 84 percent were confirmed positive for THC using the proposed 2 ng/mL confirmatory test cutoff. Only 51 percent would have confirmed positive for THCA using a 0.010 ng/mL cutoff.

Also, testing for THCA requires a larger sample volume than testing for THC. This may affect the ability of a laboratory to perform additional testing as required. To avoid the risk of positive test results from passive exposure, some investigators have recommended that THCA be included in confirmatory testing.[74 76 77 78 80] THCA occurs in oral fluid as a result of passive diffusion from blood [66] and is not found in marijuana smoke.[81] Consequently, the presence of THCA provides evidence of active use of products containing THC (*e.g.,* marijuana, dronabinol). However, based on information provided from recent studies,[82] it does not appear that THCA is reliably present in oral fluid specimens for some marijuana users: a marijuana user's oral fluid specimen may be positive for THC and negative for THCA.

A number of passive exposure studies have been conducted under a variety of exposure conditions.[58 67 80 83] Two studies reported that false results for THC were a problem if oral fluid was collected in a contaminated environment.[67 80] One passive inhalation study in which oral fluid specimens were collected in a clean environment reported no specimens positive for THC at a confirmatory cutoff concentration of 1.5 ng/mL throughout an 8-hour monitoring period following exposure.[67] A recent study [80] reported negative results for total THCA at a limit of quantification of 0.002 ng/mL, but found positive results for THC in oral fluid when specimens were collected during three hours of continuous passive exposure. Specimens collected 12 to 22 hours after passive exposure were negative for total THCA and were predominantly negative for THC; however, two of 10 specimens contained detectable amounts of THC (1.0, 1.1 ng/mL) that are well below the proposed 4 ng/mL cutoff for the initial test and 2 ng/mL cutoff for the confirmatory test.

The Department is not aware of any studies that demonstrate passive exposure causing a positive oral fluid THC result when the donor would not be aware of that exposure. Nor does there appear to be evidence that incidental exposure to marijuana smoke can cause an oral fluid specimen to be reported positive for THC using the proposed cutoff levels. Therefore, passive exposure would not be a reasonable defense for a positive result for THC in oral fluid testing.

The Department recognizes that THCA testing may be useful, because THC and THCA may be present singly or in combination in a marijuana user's oral fluid specimen depending on the length of time between use and collection. However, Current technology for conducting a confirmatory test for THCA at pg/mL concentrations requires the use of specialized materials, instrumentation, and methods.[72 73 84] In addition, a substantial portion of the oral fluid specimen may be consumed in the analytical process, thus making it difficult for a laboratory to confirm multiple initial positive drug tests or

reanalyze these specimens. Therefore, the Department is specifically interested in obtaining information on the ability of laboratories to conduct initial and/or confirmatory tests for THCA, as well as the cost of conducting the confirmatory test.

*Cocaine*

The Department is proposing to test for cocaine/benzoylecgonine using an initial cutoff concentration of 15 ng/mL and 8 ng/mL for the confirmatory cutoff concentrations. Cocaine appears in oral fluid within minutes after use following intravenous, nasal and smoked administration.[36] Cocaine is rapidly metabolized to benzoylecgonine that also is excreted in oral fluid. At different times after use, cocaine and benzoylecgonine may be present singly or in combination in oral fluid. The current proposed initial test cutoff for cocaine/benzoylecgonine (15 ng/mL) is lower than that proposed in the 2004 proposed revisions to the Guidelines (20 ng/mL). This change is justified because of the recognition that different combinations of cocaine analytes may be present at different times after use and for enhanced sensitivity for the detection of each analyte.

An immunoassay initial test for cocaine/benzoylecgonine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 15 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 8 ng/mL confirmatory test cutoff concentration applies equally to cocaine and benzoylecgonine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 8 ng/mL.

*Codeine/morphine*

The Department is proposing to test for codeine/morphine using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentrations. After single oral use, codeine has been reported to appear in oral fluid within an hour, quickly reach maximum concentration and decline over a period of approximately 24 hours.[85] An earlier study showed that codeine appeared in urine within an hour of dosing, and was detectable up to four days.[86] A metabolite of codeine, norcodeine, was also detected in oral fluid, but morphine was not detected. Although there is high variability, codeine oral fluid concentrations have been significantly correlated with plasma codeine concentrations.[85 87] Codeine undergoes extensive metabolism in the body. Two important, but minor metabolites of codeine are morphine and hydrocodone.[88 89 90] Morphine may be present in oral fluid as a result of administration of morphine,[91 92] heroin,[35] or ingestion of poppy seeds.[37] A study of morphine levels in urine and oral fluid following ingestion of poppy seeds indicated that morphine was positive for a shorter period of time (approximately 2 hours) compared to urine (approximately 8 hours).[37] A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that approximately 12.5 percent of specimens positive for morphine or codeine were positive in the concentration range of 30 to 39.9 ng/mL and would have been reported negative using a 40 ng/mL confirmatory cutoff concentration.[40] The current proposed initial test cutoff concentration (30 ng/mL) and confirmatory test cutoff concentration (15 ng/mL) for codeine/morphine are lower than those in the 2004 proposed revisions to the Guidelines (40 ng/mL for initial test and confirmatory test), primarily due to the enhanced sensitivity especially for the detection of morphine.

An immunoassay initial test for codeine/morphine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to codeine and morphine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

*6-Acetylmorphine*

The Department is proposing to test for 6-acetylmorphine using a 3 ng/mL cutoff concentration for the initial test and 2 ng/mL for the confirmatory test cutoff concentration. 6-acetylmorphine, a unique metabolite of heroin, appears in oral fluid within minutes following smoked or injected heroin administration.[35] A high prevalence of 6-acetylmorphine in oral fluid specimens following heroin use has been reported,[93–96] suggesting it may offer advantages over urine in workplace testing programs. An initial assay for 6-acetylmorphine separate from a general opiates assay is currently used in the UrMG. The 2004 proposed revisions to the Guidelines did not propose a separate initial test for 6-acetylmorphine. An initial test for 6-acetylmorphine is proposed because of the recent recognition that 6-acetylmorphine may be positive in oral fluid specimens that would not initially test positive for opiates.[35 94] A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that 12.5 percent of specimens positive for 6-acetylmorphine were positive in the concentration range of 3 to 3.9 ng/mL and would have been reported negative at a 4 ng/mL confirmatory cutoff concentration.[40] The current proposed confirmatory test cutoff concentration (2 ng/mL) for 6-acetylmorphine is lower than in the 2004 proposed revisions to the Guidelines (4 ng/mL), primarily for enhanced sensitivity.

*Phencyclidine*

The Department is proposing to test for phencyclidine using a 3 ng/mL cutoff concentration for the initial test and 2 ng/mL for the confirmatory test cutoff concentration. Phencyclidine has been measured in oral fluid following different routes of administration. [97 98] A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that 57.1 percent of specimens positive for phencyclidine were positive in the concentration range of 1.5 to 9.9 ng/mL and would have been reported negative at a 10 ng/mL confirmatory cutoff concentration.[40] The current proposed initial test cutoff concentration (3 ng/mL) and confirmatory test cutoff concentration (2 ng/mL) for phencyclidine are lower than those in the 2004 proposed revisions to the Guidelines (10 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity.

*Amphetamine/methamphetamine*

The Department is proposing to test for amphetamine/methamphetamine using a 25 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. Amphetamine appears rapidly in oral fluid following administration [99] and, although variable, correlates with blood concentrations in drivers suspected of driving under the influence of drugs.[100] Methamphetamine and its metabolite, amphetamine, also appear rapidly in oral fluid and plasma following administration. [101] [102] In one study,[102] concentrations of amphetamine relative to methamphetamine in oral fluid ranged from 16 percent to 37 percent following methamphetamine administration. The positivity rate for methamphetamine in oral fluid was highly influenced by the requirement for detection of amphetamine metabolite in the study. When the confirmatory cutoff concentration for methamphetamine was 50 ng/mL and detection of amphetamine at 2.5 ng/mL (limit of detection) was applied to oral fluid specimens, only 1 of 13 individuals tested positive 24 hours after a single methamphetamine dose and; only 23 of 130 (18 percent) specimens tested positive within 24 hours after dosing. The current proposed initial test cutoff concentration (25 ng/mL) and confirmatory test cutoff concentration (15 ng/mL) for amphetamine/methamphetamine are lower than those in the 2004 proposed revisions to the Guidelines (50 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity. There is no proposed reporting requirement for a methamphetamine-positive specimen to contain amphetamine as there is in the UrMG.

An immunoassay initial test for amphetamine/methamphetamine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 25 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to amphetamine and methamphetamine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

*Methylenedioxymethamphetamine (MDMA)/Methylenedioxyamphetamine (MDA)/ Methylenedioxyethylamphetamine (MDEA)*

The Department is proposing to test for MDMA/MDA/MDEA using a 25 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. MDMA appears in oral fluid approximately 0.25–1.5 hours following oral administration and demonstrates similar kinetic patterns as plasma concentrations.[103–105] MDMA is metabolized by N-demethylation to MDA, a compound that exhibits similar psychoactive properties to MDMA. As a metabolite of MDMA, MDA is excreted in oral fluid with concentrations representing approximately 4–5 percent of MDMA.[104] MDEA also is metabolized by N-dealkylation to MDA as an active metabolite.[106] MDEA has been reported in oral fluid specimens collected from recreational drug users in concentrations ranging from 25 to 3320 ng/mL.[105] The current recommended initial test concentration (25 ng/mL) and confirmatory test cutoff concentration (15 ng/mL) for MDMA/MDA/MDEA are lower than those in the 2004 proposed revisions to the Guidelines (50 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity.

An immunoassay initial test for MDMA/MDA/MDEA should be calibrated with one of the three analytes and demonstrate sufficient cross-reactivity with each analyte. The Department recommends that the minimum cross-reactivity with each analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or all analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the three analytes must be equal to or greater than 25 ng/mL. The quantitative sum of the three analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to MDMA, MDA and MDEA. A positive test would be comprised of one or more of the three analytes with a confirmed concentration equal to or greater than 15 ng/mL.

*Inclusion of Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone*

Misuse and abuse of psychotherapeutic prescription drugs, including opoid pain relievers, are issues of concern for all populations regardless of age, gender, ethnicity, race, or community. Recent data show that opoid-related overdose deaths in the U.S. now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined. In addition to overdose deaths, emergency department visits, substance abuse treatment admissions, and economic costs associated with opioid abuse have all increased in recent years. The Department is continuing to work with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug abuse and improve public health.[107]

The Department proposes the inclusion of additional Schedule II prescription medications (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the list of authorized drug tests and cutoff concentrations. This action was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and received by the SAMHSA Administrator in January 2012. The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone is supported by various data. According to the 2012 National Survey on Drug Use and Health, which provides data on illicit drug use in the U.S., current (past month) nonmedical users aged 12 years and older of prescription psychotherapeutic drugs increased from 2003 (6.5 million) to 2012 (6.8 million).[59] Psychotherapeutic drugs are defined as opioid pain relievers, tranquilizers, sedatives, and stimulants. The abuse of psychotherapeutic drugs non-medically is ranked second behind marijuana, where pain relievers represent the majority of the group. The Drug Abuse Warning Network (DAWN) Report, which provides national estimates of drug-related visits to hospital emergency departments (ED), showed that of the 1.2 million ED visits involving nonmedical use of pharmaceuticals in 2011, 46.0 percent of visits involved nonmedical use of pain relievers, with 29 percent being narcotic pain relievers.[60] The most frequently involved narcotic pain relievers were oxycodone and hydrocodone. From 2004 to 2011, ED visits involving nonmedical use of narcotic pain

relievers increased by 153 percent. ED visits involving opiates/opioids increased by 183 percent during this period, with increases of 438 percent for hydromorphone, 263 percent for oxycodone, and over 100 percent for hydrocodone, as well as fentanyl and morphine. In addition, the National Forensic Laboratory Information System (NFLIS) found that oxycodone and hydrocodone were among the top ten drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories.[61] Among prescription drugs, oxycodone and hydrocodone ranked first and second. Information on over 5 million drug tests in general workplace drug testing shows that the positivity rate for oxycodone and hydrocodone (0.96%) was second only to marijuana in 2012.[39]

The use of medications, specifically Schedule II drugs, without a prescription is a growing concern for the Department in workplace drug testing, and the proposal for their inclusion offers the opportunity to deter nonmedical use of these drugs among federal workers. The Department does note that in recognition of the prescription drug abuse issue, the Department of Defense issued a memorandum on January 30, 2012, announcing the expansion of their drug testing panel to include hydrocodone and benzodiazepines starting on May 1, 2012. Similarly, the Department proposes that federal agencies include the testing of oxycodone, oxymorphone, hydrocodone, and hydromorphone in oral fluid specimens as described below.

*Oxycodone/oxymorphone*

The Department is proposing to test for oxycodone/oxymorphone using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentrations. Both oxycodone and oxymorphone have been reported to be readily detectable in oral fluid specimens collected from pain patients.[41 108] Oxycodone is metabolized in relatively minor amounts to oxymorphone.[63] Oxymorphone is a potent analgesic used for pain relief orally and parenterally, and is primarily metabolized by conjugation.[109]

An immunoassay initial test for oxycodone/oxymorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to oxycodone and oxymorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

*Hydrocodone/hydromorphone*

The Department is proposing to test for hydrocodone/hydromorphone using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. Hydromorphone appears rapidly in oral fluid following intravenous administration and follows a similar kinetic profile as that observed in plasma.[110] Both hydrocodone and hydromorphone have been reported to be readily detectable in oral fluid specimens collected from pain patients.[41 108] Hydrocodone is metabolized in relatively minor amounts to hydromorphone.[62] Hydromorphone is a potent analgesic used for pain relief orally and parenterally, and is primarily metabolized by conjugation.[111] Hydrocodone has been reported to be a minor metabolite of codeine [90] and hydromorphone has been reported to be a minor metabolite of morphine.[112 113]

An immunoassay initial test for hydrocodone/hydromorphone should be calibrated with one of the two analytes and demonstrate sufficient cross reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to hydrocodone and hydromorphone. A positive test would be comprised of either or both analytes with a confirmed equal to or greater than 15 ng/mL.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination drug products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, in October 2013, the FDA Center for Drug Evaluation and Research announced the agency's intent to recommend to HHS that hydrocodone combination drug products should be reclassified to Schedule II. FDA stated that this determination came after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which FDA received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

In December 2013, FDA, with the concurrence of the National Institute on Drug Abuse (NIDA), submitted a formal recommendation package to HHS to reclassify hydrocodone combination drug products into Schedule II. Also in December 2013, the Secretary of HHS submitted the scientific and medical evaluation and scheduling recommendation to the DEA for its consideration. On August 22, 2014, DEA published the Final Rule that moves hydrocodone combination drug products from Schedule III to Schedule II.

Section 3.5 authorizes HHS-certified laboratories to perform additional tests to assist the MRO in making a determination of positive or negative results. The Department believes that additional tests can be requested by the MRO to further inform them to determine the veracity of the medical explanation of the donor. An example of an additional test currently requested by an MRO is when the laboratory reports a positive methamphetamine result. The MRO may request a d,l-stereoisomer determination for methamphetamine, to determine whether the result could be attributed to use of an over-the-counter nasal inhaler. Another example of current practice is when the laboratory reports a positive THCA result, and the MRO requests testing for cannabivarin, to distinguish marijuana use from dronabinol (*e.g.,* Marinol®).

Section 3.6 includes criteria for reporting an oral fluid specimen as adulterated. While there are no known oral fluid adulterants at this time, the Department is proposing to establish criteria similar to that for urine specimens, to ensure procedures that are forensically acceptable and

scientifically sound, while allowing laboratories the flexibility necessary to develop specific testing requirements for an adulterant.

Section 3.7 incorporates criteria from the UrMG that are applicable for reporting an invalid result for an oral fluid specimen, and includes an additional criterion to enable laboratories to perform specimen validity testing using biomarkers other than IgG and albumin.

**Subpart D—Collectors**

Sections 4.1 through 4.5 contain the same policies as described in the current UrMG in regard to who may or may not collect a specimen, the requirements to be a collector, the requirements to be a trainer for collectors, and what a federal agency must do before a collector is permitted to collect a specimen.

**Subpart E—Collection Sites**

Sections 5.1 through 5.5 address requirements for collection sites, collection site records, how a collector ensures the security and integrity of a specimen at the collection site, and the privacy requirements when collecting a specimen.

**Subpart F—Federal Drug Testing Custody and Control Form**

Sections 6.1 and 6.2 are the same as in the current UrMG, requiring an OMB-approved Federal CCF be used to document custody and control of each specimen at the collection site, and specifying what should occur if the correct OMB-approved CCF is not used.

**Subpart G—Oral Fluid Specimen Collection Devices**

Section 7.1 describes the type of collection device that must be used to collect an oral fluid specimen. A single use device that has been cleared by the FDA for the collection of oral fluid must be used.

Section 7.2 describes specific requirements for the oral fluid collection device, to ensure that the device provides a sufficient volume for laboratory analysis and maintains the integrity of the specimen. The Department has determined that it is essential that the device have a volume adequacy indicator showing that a minimum volume of 1 mL oral fluid has been collected; that the container be sealable and non-leaking; and that all components of the device ensure drug and metabolite stability and do not substantially affect the composition of drug and/or drug metabolites in the specimen.

Section 7.3 details the minimum performance requirements for a collection device. Considering the variety of oral fluid collection devices available, the Department considers it necessary to require that any device used meet minimum standards to ensure the integrity of the specimen and the standardization of the laboratory analysis process.

**Subpart H—Oral Fluid Specimen Collection Procedure**

This subpart addresses the same topics, in the same order, as the UrMG procedures for urine specimen collection.

Section 8.1 specifies the procedures required to provide privacy for the oral fluid donor during the collection procedure.

Sections 8.2 through 8.5 describe the responsibilities and procedures the collector must follow before, during, and after an oral fluid collection.

Section 8.6 describes the procedures the collector must follow when a donor is unable to provide an oral fluid specimen.

Section 8.7 prohibits collection of an alternate specimen when a donor is unable to provide an adequate oral fluid specimen, unless specifically authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs and by the federal agency.

Section 8.8 describes how the collector prepares the oral fluid specimens, including the description of the oral fluid split specimen collection.

Section 8.9 specifies how a collector is to report a refusal to test.

Section 8.10 is the same as that in the UrMG in regard to federal agency responsibilities for ensuring that each collection site complies with all provisions of the Mandatory Guidelines. An example of appropriate action that may be taken in response to a reported collection site deficiency is self-assessment using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs. This document will be available on the SAMHSA Web site *http://www.samhsa.gov/workplace/drug-testing.*

**Subpart I—HHS-Certification of Laboratories**

This subpart addresses the same topics for HHS certification of laboratories to test oral fluid specimens, as are included in the UrMG for HHS certification of laboratories to test urine specimens.

Sections 9.1 through 9.4 contain the same policies as in the current UrMG for laboratories to become HHS-certified and to maintain HHS certification to conduct oral fluid testing for a federal agency, as well as what a laboratory must do when certification is not maintained.

Section 9.5 contains specifications for PT samples, Section 9.6 contains PT requirements for an applicant laboratory, and Section 9.7 contains PT requirements for an HHS-certified laboratory. These sections incorporate the applicable requirements from the current UrMG, but exclude UrMG requirements that are specific for urine testing and include those specific for oral fluid testing.

The remaining Sections 9.8 through 9.17 contain the same policies as the UrMG. These sections address inspection requirements for applicant and HHS-certified laboratories, inspectors, consequences of an applicant or HHS-certified laboratory failing to meet PT or inspection performance requirements, factors considered by the Secretary in determining the revocation or suspension of HHS-certification, the procedure for notifying a laboratory that adverse action (*e.g.,* suspension or revocation) is being taken by HHS, and the process for re-application once a laboratory's certification has been revoked by the Department.

Section 9.17 states that a list of laboratories certified by HHS to conduct forensic drug testing for federal agencies will be published monthly in the **Federal Register**. The list will indicate the type of specimen (*e.g.,* oral fluid or urine) that each laboratory is certified to test.

**Subpart J—Blind Samples Submitted by an Agency**

This subpart (Sections 10.1 through 10.4) describes the same policies for federal agency blind samples as the UrMG, with two exceptions. Oral fluid blind samples that challenge specimen validity tests are not required, and the blind supplier must validate blind samples in the selected manufacturer's collection device.

**Subpart K—Laboratory**

This subpart addresses the same topics, in the same order, as the UrMG procedures for laboratories testing urine specimens. As appropriate, the section includes requirements that are specific for oral fluid testing.

Sections 11.1 through 11.8 include the same requirements that are contained in the current UrMG for the laboratory standard operating procedure (SOP) manual; responsibilities and scientific qualifications of the

responsible person (RP); procedures in the event of the RP's extended absence from the laboratory; qualifications of the certifying scientists, certifying technicians, and other HHS-certified laboratory staff; security; and chain of custody requirements for specimens and aliquots.

Sections 11.9 through 11.14 include the same requirements as in the current UrMG in regard to initial and confirmatory drug test requirements, validation, and batch quality control as described in each section below.

Section 11.9 describes the requirements for the initial drug test which permit the use of an immunoassay or alternate technology (*e.g.,* spectrometry or spectroscopy). The Department believes that new technology has advanced in the initial testing for drugs, and does not want to limit the testing technology to immunoassay.

Sections 11.10 and 11.11 cover validation and quality control requirements for the initial test.

Section 11.12 describes the requirements for a confirmatory drug test. The Department proposes to allow analytical procedures using mass spectrometry or other equivalent technologies. Based on ongoing reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied newer instruments and technologies, the Department believes that scientifically valid confirmatory methods other than combined chromatographic and mass spectrometric methods can be used to successfully detect and report the cutoff concentrations proposed in Subpart C-Oral Fluid Specimen Drug Tests.

Sections 11.13 and 11.14 cover validation and quality control requirements for the confirmatory tests.

Sections 11.15 and 11.16 address specimen validity tests that a laboratory performs for oral fluid specimens. The Department included requirements in the OFMG to test all specimens for albumin or IgG and to allow laboratories to perform other specimen validity tests. All specimen validity tests must use appropriate analytical methods that are properly controlled and validated, to provide scientifically supportable and forensic acceptable results to the MRO.

Section 11.17 describes in detail how a certified laboratory is required to report test results to MRO for oral fluid specimens.

Sections 11.18 and 11.19 contain the same requirements as the UrMG for specimen and record retention.

Section 11.20 describes the statistical summary report that a laboratory must provide to a federal agency for oral fluid testing. This section is comparable to the same section in the UrMG, differing only in that the statistical report elements are specific for oral fluid testing.

Section 11.21 addresses the laboratory information to be made available to a federal agency and describes the contents of a standard laboratory documentation package. This is the same policy as in the UrMG.

Section 11.22 addresses the laboratory information to be made available to a federal employee upon written request through the MRO, and clarifies that specimens are not a part of the information package that donors can receive from HHS-certified laboratories. This is the same policy as in the UrMG.

The remaining section, Section 11.23, describes the relationships that are prohibited between an HHS-certified laboratory and an MRO. These are the same as in the UrMG.

**Subpart L—Instrumented Initial Test Facility (IITF)**

This subpart emphasizes that federal agencies may choose to use IITFs for urine testing but not for oral fluid testing. Section 12.1 clearly states that only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs. Instrumented Initial Test Facilities are not practical and will not be allowed due primarily to the limited sample volume of oral fluid collected from the donor.

**Subpart M—Medical Review Officer (MRO)**

This subpart addresses the same topics, in the same order, as the UrMG procedures for Medical Review Officers (MROs).

Section 13.1 describes who may serve as an MRO. With the inclusion of additional Schedule II prescription medications in the Mandatory Guidelines and the ever-changing field of drug testing, medical review of drug test results is more complex today than before. Therefore, the Department proposes to incorporate MRO requalification training and reexamination on a regular basis (at least every five years). The URMG and OFMG do not include a requirement for MROs to obtain continuing education units (CEUs). The Department understands that it would be difficult to determine whether CEUs obtained are related to federal agency drug testing. The requalification requirement every five years will assure agency auditors and inspectors and regulated employers that MROs are appropriately qualified. This requirement is not expected to increase costs to MROs. Current practices for MRO requirements have equivalent standards but vary among MRO training entities. These requirements will standardize the length of time each MRO is required to take a requalification examination. Currently, some MRO requalification periods are longer than five years, while others are less than five years. The Department assumes that the costs to those MROs that have requalification periods over five years will be offset by the cost savings to MROs that have periods shorter than five years. Thus, the Department has not estimated any costs associated with this provision, but it welcomes comment on this assumption.

The Department anticipates that MROs will continue to obtain CEUs by virtue of maintaining their medical licensure requirements. In addition, the MRO certification/training entities provide MRO manuals and periodic newsletters with updates on federal drug testing program requirements. However, the Department is seeking comments on requiring MRO requalification CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification.

MROs play a key role in the federal safety program and maintain the balance between the safety and privacy objectives of the program. The MRO's role in gathering and evaluating the medical evidence and providing due process is imperative. These are duties that must be carried out by the MRO and cannot be delegated to other personnel who are not certified by an MRO entity.

The MRO is charged with certain important medical and administrative duties. The MRO must have detailed knowledge of the effects of medications and other potential alternative medical explanations for laboratory reported drug test results. He or she is responsible for determining whether legitimate medical explanations are available to explain an employee's drug test result. This medical review process has become far more complex as a result of specimen validity testing and the myriad of medical explanations for adulterated, substituted, and invalid laboratory test results. These complexities have made MRO knowledge of the effects of drugs and medications even more important.

In addition, MROs confer with prescribing physicians in making decisions about prescription changes so that alternative medications can be used that will not impact public safety. Similarly, the MRO is required to report

to employers the employees' prescription and over-the-counter medication use (or dangerous combinations of use) that the MRO believes will negatively affect duty performance. In addition, the MRO is required to medically assess referral physician examinations and evaluations in certain positive and refusal-to-test situations. These, too, have become more complex over time.

Section 13.2 describes how nationally recognized entities or subspecialty boards that certify MROs are approved.

Section 13.3 describes the training that is required before a physician may serve as an MRO. The Department has added a requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. MROs performing the review of federal employee drug test results should be aware of prevention and treatment opportunities for individuals and can provide information to the donor.

Section 13.4 describes the responsibilities of an MRO.

Section 13.5 describes an MRO's actions when reviewing an oral fluid specimen's test results. This section includes procedures that are specific to oral fluid specimen results.

In Section 13.5, item c(2)(ii), the Department proposes a morphine or codeine confirmatory concentration that the MRO verifies as positive without requiring clinical evidence of illegal drug use, when the donor does not have a legitimate medical explanation. As in the UrMG, this section states that the MRO must not consider consumption of food products as a legitimate explanation for the donor having morphine or codeine at or above the specified concentration in his or her oral fluid. There is limited information in the scientific literature on the codeine and/or morphine concentrations seen in oral fluid after consumption of poppy seed food products. Therefore, the Department is proposing a conservative concentration of 150 ng/mL (*i.e.,* 10 times the confirmatory test cutoff) as the decision point. The Department specifically requests public comment on the appropriateness of this concentration.

Section 13.6 describes what an MRO must do when the collector reports that a donor did not provide a sufficient amount of oral fluid for a drug test. This section contains the same procedures as the UrMG, with information specific to oral fluid specimens.

Section 13.7 describes what an MRO must do when a donor has a permanent or long-term medical condition that prevents him or her from providing a sufficient amount of oral fluid for a federal agency applicant/pre-employment, follow-up, or return-to-duty test. These procedures are the same as in the UrMG.

The remaining sections, Sections 13.8, 13.9, and 13.10, are the same as in the UrMG, addressing who may request a test of the split (B) specimen, how an MRO reports a primary (A) specimen result, and the types of relationship that are prohibited between an MRO and an HHS- certified laboratory.

**Subpart N—Split Specimen Tests**

Sections 14.1 and 14.2 include the same policies as the UrMG in regard to when a split (B) specimen may be tested and the testing requirements for a split specimen when the primary specimen was reported positive for a drug(s).

Section 14.3 specifies how the split testing laboratory tests a split (B) oral fluid specimen when the primary (A) specimen was reported as adulterated. As noted previously in this Preamble, the Department is not aware of any adulterants being used for oral fluid specimens, but has included policies in these Guidelines to allow for the testing and reporting of adulterants in oral fluid.

Section 14.4 includes the same policy as the UrMG, requiring the laboratory to report the split (B) specimen result to the MRO.

In Section 14.5, the Department is proposing the actions an MRO must take after receiving the split (B) specimen result. This section is analogous to the corresponding section in the UrMG, with differences where applicable for oral fluid specimen reports.

Section 14.6 is the same as the UrMG in regard to how an MRO reports a split (B) specimen result to an agency.

Section 14.7 is the same as the UrMG, requiring the HHS-certified laboratory to retain a split oral fluid specimen for the same length of time that the primary specimen is retained.

**Subpart O—Criteria for Rejecting a Specimen for Testing**

Sections 15.1 and 15.2 contain the same policies as the current UrMG for discrepancies requiring a laboratory to reject a specimen and for discrepancies that require a laboratory to reject a specimen unless the discrepancy is corrected.

Section 15.3 lists those discrepancies that would not affect either testing or reporting of an oral fluid specimen result. These are similar to the corresponding section in the UrMG, with differences where applicable for oral fluid specimens.

Section 15.4 describes the discrepancies that may require the MRO to cancel a test, which are the same as those in the UrMG.

**Subpart P—Laboratory Suspension/ Revocation Procedures**

In this subpart, the Department proposes the same procedures that are described in the UrMG to revoke or suspend the HHS-certification of laboratories.

**Impact of These Guidelines on Government Regulated Industries**

The Department is aware that these proposed new Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final OFMG into their programs under their own authority.

**Topics of Special Interest**

The Department requests public comment on all aspects of this notice. However, the Department is providing the following list of areas for which specific comments are requested.

Section 3.1 requires federal agencies to test all oral fluid specimens for either albumin or IgG to determine specimen validity. The Department specifically requests public comment on this requirement.

Section 3.4 lists the proposed cutoff concentrations. The Department is specifically requesting comments on the appropriateness of these proposed cutoffs.

Regarding Section 3.4, the Department is specifically interested in obtaining information on the capability of laboratories to test THCA analyte using a cutoff of 50 pg/mL and the validity of whether THCA can be established as an accurate, sensitive and valid marker for oral fluid testing to detect marijuana use. Additionally, the Department is interested in obtaining information whether THCA should be used to extend the window of detection of marijuana use. The Department is also interested in receiving comments on lowering the cutoff concentration for delta-9-tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff concentration and to 1 ng/mL for the confirmatory cutoff concentration to extend the window of detection.

In section 7.3, the Department proposes performance requirements for a collection device. The Department is requesting specific comments on these requirements.

In Section 13.5, the Department proposes a concentration of 150 ng/mL morphine or codeine be used by the

MRO to report a positive result in the absence of a legitimate medical explanation (*i.e.,* prescription), without requiring clinical evidence of illegal opiate use, and to rule out the possibility of a positive result due to consumption of food products. The Department is requesting specific comments on this proposed concentration.

**Regulatory Impact and Notices**

The Department welcomes public comment on all figures and assumptions described in this section.

*Executive Orders 13563 and 12866*

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) states ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' This notice proposes a regulatory approach that will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the proposed Guidelines under Executive Order 12866, which directs federal 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). In addition, the Department published a **Federal Register** notice in June 2011 to solicit comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086].

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The proposed Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

*Need for regulation*

Enhances Flexibility

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will provide flexibility to address workplace drug testing needs of federal agencies while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results.

Enhances Versatility

Medical conditions exist that may prevent a federal employee or applicant from providing sufficient urine or oral fluid for a drug test. When the OFMG are implemented, in the event that an individual is unable to provide a urine specimen, the federal agency may authorize the collection of an oral fluid specimen. In the event a federal agency adopts oral fluid testing and the donor is unable to collect an oral fluid specimen, the federal agency may also authorize the collection of a urine specimen. This will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen.

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. An acceptable oral fluid collection site must allow the collector to observe the donor, maintain control of the collection device(s) during the process, maintain record storage, and protect donor privacy.

Decreases Invalid Tests

Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. All oral fluid specimens will be tested for either albumin or immunoglobulin G (IgG) to identify invalid specimens.

Saves Time

Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer. Oral fluid collection does not require a facility that provides visual privacy during the collection. It is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace. The collector is allowed to be in the vicinity of the donor, reducing the loss of productive time. The option to collect a urine specimen in the event that the donor cannot provide an oral fluid specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a specimen. Administrative data indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be between 1 and 3 hours. This range reflects uncertainty around the location of the collection. The lower bound represents an estimate of time savings if the collection was conducted at an offsite location. The upper bound estimate represents the time savings if the collection was conducted at the employee's workplace, and thus incorporates travel time savings. Using OPM's estimate for the average annual salary of Federal employees converted to an hourly wage, the savings generated for the Federal Government would be roughly $400,000 to $1.2 million a year, or $38 to $114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are

dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Advances in Oral Fluid Drug Testing

In the past, urine was the only permitted specimen for forensic workplace drug testing. However, some issues that previously deterred the use of oral fluid for drug testing have been resolved. The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. In addition, OFMG analyte cutoff concentrations are much lower than those specified for urine in the Guidelines. Additionally, specimen volume is also much lower, saving time in collection and transport cost. Developments in analytical technologies have allowed their use as efficient and cost-effective methods that provide the needed analytical sensitivity and accuracy for testing oral fluid specimens.

Current Testing in the Drug Free Workplace Program

Urine was the original specimen of choice for forensic workplace drug testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace.

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. Current research indicates that some current substitution products are indistinguishable from human urine. The use of these products is expected to continue.

Time Horizon of This Analysis

The transition to the testing of oral fluids will be gradual and steady over the course of four years, when it should plateau. By this time, it is expected that oral fluid tests will account for 25–30% of all regulated drug testing. This estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the past four years.

Cost and Benefit

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. HHS projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS certified laboratories currently testing non-regulated oral fluid specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA and MDEA since current immunoassays can be adapted to test for these analytes. Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the NLCP. Estimated laboratory costs to complete and submit the application are $2,000, and estimated costs for the Department to process the application are $7,200. These estimates are from SAMHSA are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that their performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each applicant laboratory.

Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $54,000 and $69,000. This training cost is included in the costs of the revised URMG.

*Summary of One-Time Costs*

| | Lower bound | Upper bound | Primary |
|---|---|---|---|
| Cost of Application * | | | $62,000.00 |
| Application Processing * | | | 217,000.00 |
| Performance Testing * | 27,900.00 | 55,800.00 | |
| Training * | 54,000.00 | 69,000.00 | |

| | Lower bound | Upper bound | Primary |
|---|---|---|---|
| Total | 360,900.00 | 403,800.00 | |

* Estimated using costs presented above multiplied by the number of laboratories (31).

*Costs and Benefits*

Thus, the Department estimates one-time, upfront costs of between $360,000 and $400,000. While the Department has only monetized a small portion of the benefits (time savings) to a small subset of the workplace drug testing programs that could be affected by the OFMG (*i.e.,* Federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the costs. Even if NRC and DOT do not implement oral fluid testing, the benefits to Federal workplace testing programs, estimated at between $400,000 and $1.2 million, would recur on annual basis.

*Regulatory Flexibility Analysis*

For the reasons outlined above, the Secretary has determined that the proposed Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the OFMG will not require addition expenditures. Therefore, an initial regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Orders 13563 and 12866, the Secretary anticipates that there will be an overall reduction in costs if drug testing is expanded under the OFMG. The costs to implement this change to regulation are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the originally authorized specimen type. Insofar as there are costs associated with each drug test, this could lead to lower overall testing costs for federal agencies. The added flexibility will also benefit federal employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

The Secretary has determined that the proposed Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

*Unfunded Mandates*

The Secretary has examined the impact of the proposed Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the proposed Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

*Environmental Impact*

The Secretary has considered the environmental effects of the OFMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

*Executive Order 13132: Federalism*

The Secretary has analyzed the proposed Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary is proposing to establish standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

*Paperwork Reduction Act of 1995*

The proposed Guidelines contain information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 [the PRA 44 U.S.C. 3507(d)]. Information collection and recordkeeping requirements which would be imposed on laboratories engaged in drug testing for federal agencies concern quality assurance and quality control documentation, reports, performance testing, and inspections as set out in subparts H, I, K, L, M and N. To facilitate ease of use and uniform reporting, a Federal CCF for each type of specimen collected will be developed as referenced in section 6.1. The Department has submitted the information collection and recordkeeping requirements contained in the proposed Guidelines to OMB for review and approval.

*Privacy Act*

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug

Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

*Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The proposed Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

**Information Collection/Recordkeeping Requirements**

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect until final Guidelines including the use of oral fluid specimens are issued.

The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens.

*Description:* The Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930–0158. Since 1988, several products have appeared on the market making it easier for individuals to adulterate the urine specimen. Scientific advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. The proposed Guidelines establish when oral fluid specimens may be collected, the procedures that must be used in collecting an oral fluid specimen, and the certification process for approving a laboratory to test oral fluid specimen.

*Description of Respondents:* Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

*The burden estimates in the tables below are based on the following number of respondents:* 38,000 donors who apply for employment in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 9.2(a)(1) | Laboratory required to submit application for certification. | 10 | 1 | 3 | 30 |
| 9.10(a)(3) | Materials to submit to become an HHS inspector. | 10 | 1 | 2 | 20 |
| 11.3(a) | Laboratory submits qualifications of RP to HHS. | 10 | 1 | 2 | 20 |
| 11.4(c) | Laboratory submits information to HHS on new RP or alternate RP. | 10 | 1 | 2 | 20 |
| 11.20 | Specifications for laboratory semi-annual statistical report of test results to each federal agency. | 10 | 5 | 0.5 | 25 |
| 13.9 & 14.6 | Specifies that MRO must report all verified split specimen test results to the federal agency. | 100 | 5 | *0.05 | 25 |
| 16.1(b) & 16.5(a) | Specifies content of request for informal review of suspension/proposed revocation of certification. | 1 | 1 | 3 | 3 |

ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 16.4 | Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed. | 1 | 1 | 0.5 | 0.5 |
| 16.6 | Requires appellant to notify reviewing official of resolution status at end of abeyance period. | 1 | 1 | 0.5 | 0.5 |
| 16.7(a) | Specifies contents of appellant submission for review. | 1 | 1 | 50 | 50 |
| 16.9(a) | Specifies content of appellant request for expedited review of suspension or proposed revocation. | 1 | 1 | 3 | 3 |
| 16.9(c) | Specifies contents of review file and briefs | 1 | 1 | 50 | 50 |
| Total | | 156 | | | 247 |

*3 min.

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refuse to participate in the collection process on the Federal CCF (sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); MRO notifies the federal agency and HHS when an error occurs on a blind sample (section 10.4(c)); section 13.5 describes the actions an MRO takes to report a primary specimen result; and section 14.5 describes the actions an MRO takes to report a split specimen result. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 8.3(a) & 8.6(b)(2) | Collector must contact federal agency point of contact. | 100 | 1 | *0.05 | 5 |
| 11.21 & 11.22 | Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO. | 10 | 10 | 3 | 1,500 |
| 13.8(b) | MRO must inform donor of right to request split specimen test when a positive or adulterated result is reported. | 100 | 5 | 3 | 1,500 |
| Total | | 210 | | | 3,505 |

*3 min.

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: The collector must explain the basic collection procedure to the donor and answer any questions (section 8.3(f) and (h), and must review the procedures for the oral fluid specimen collection device used with the donor (section 8.4(b)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 8.3, 8.5, & 8.8 | Collector completes Federal CCF for specimen collected. | 100 | 380 | *0.07 | 2,534 |
| 8.8(d) & (f) | Donor initials specimen labels/seals and signs statement on the Federal CCF. | 38,000 | 1 | **0.08 | 3,167 |
| 11.8(a) & 11.17 | Laboratory completes Federal CCF upon receipt of specimen and before reporting result. | 10 | 3,800 | ***0.05 | 1,900 |
| 13.4(d)(4), 13.9(c), & 14.6(c). | MRO completes Federal CCF before reporting the result. | 100 | 380 | ***0.05 | 1,900 |
| 14.1(b) | MRO documents donor's request to have split specimen tested. | 300 | 1 | ***0.05 | 15 |

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN—Continued

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| Total | | 38,510 | | | 9,516 |

*4 min.
**5 min.
***3 min.

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [section 4.3(a)(3)] and the documentation must be maintained in the collector's training file [section 4.3(c)]. SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a federal agency specimen, the collector is required to provide a statement [section 6.2(b)] explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H [sections 8.4(d) and 8.5(a)(1)] requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries are included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K describe a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(1); 11.13(a); 11.16; 11.17(a), (b), and (c); 11.20; 11.21, and 11.22. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,268 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS'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.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to (202) 395–6974 (fax).

## References


1. Bosker, W.M., Huestis, M.A., 2009. Oral fluid testing for drugs of abuse. *Clin Chem,* 55, 1910–1931.
2. Caplan, Y.H., Goldberger, B.A., 2001. Alternative specimens for workplace drug testing. *J Anal Toxicol,* 25, 396–399.
3. Choo, R.E., Huestis, M.A., 2004. Oral fluid as a diagnostic tool. *Clin Chem Lab Med,* 42, 1273–1287.
4. Cone, E.J., Huestis, M.A., 2007. Interpretation of oral fluid tests for drugs of abuse. *Ann N Y Acad Sci,* 1098, 51–103.
5. Drummer, O.H., 2006. Drug testing in oral fluid. *Clin Biochem Rev,* 27, 147–159.
6. Kadehjian, L., 2005. Legal issues in oral fluid testing. *Forensic Sci Int,* 150, 151–160.
7. Pil, K., Verstraete, A., 2008. Current developments in drug testing in oral fluid. *Ther Drug Monit,* 30, 196–202.
8. Samyn, N., De Boeck, G., Verstraete, A.G., 2002. The use of oral fluid and sweat wipes for the detection of drugs of abuse in drivers. *J Forensic Sci,* 47, 1380–1387.
9. Samyn, N., Laloup, M., De Boeck, G., 2007. Bioanalytical procedures for determination of drugs of abuse in oral fluid. *Anal Bioanal Chem,* 388, 1437–1453.
10. Toennes, S.W., Kauert, G.F., Steinmeyer, S., Moeller, M.R., 2005. Driving under the influence of drugs—evaluation of analytical data of drugs in oral fluid, serum and urine, and correlation with impairment symptoms. *Forensic Sci Int,* 152, 149–155.
11. Verstraete, A.G., 2004. Detection times of drugs of abuse in blood, urine, and oral fluid. *Ther Drug Monit,* 26, 200–205.
12. Verstraete, A.G., 2005. Oral fluid testing for driving under the influence of drugs: history, recent progress and remaining challenges. *Forensic Sci Int,* 150, 143–150.
13. Allen, K.R., Azad, R., Field, H.P., Blake, D.K., 2005. Replacement of immunoassay by LC tandem mass spectrometry for the routine measurement of drugs of abuse in oral fluid. *Ann Clin Biochem,* 42, 277–284.
14. Badawi, N., Simonsen, K.W., Steentoft, A., Bernhoft, I.M., Linnet, K., 2009. Simultaneous screening and quantification of 29 drugs of abuse in oral fluid by solid-phase extraction and ultraperformance LC–MS/MS. *Clin Chem,* 55, 2004–2018.
15. Concheiro, M., de Castro, A., Quintela, O., Cruz, A., Lopez-Rivadulla, M., 2008. Determination of illicit and medicinal drugs and their metabolites in oral fluid and preserved oral fluid by liquid chromatography-tandem mass spectrometry. *Anal Bioanal Chem,* 391, 2329–2338.
16. Concheiro, M., Gray, T.R., Shakleya, D.M., Huestis, M.A., 2010. High-throughput simultaneous analysis of buprenorphine, methadone, cocaine,

opiates, nicotine, and metabolites in oral fluid by liquid chromatography tandem mass spectrometry. *Anal Bioanal Chem,* 398, 915–924.
17. Fritch, D., Blum, K., Nonnemacher, S., Haggerty, B.J., Sullivan, M.P., Cone, E.J., 2009. Identification and quantitation of amphetamines, cocaine, opiates, and phencyclidine in oral fluid by liquid chromatography-tandem mass spectrometry. *J Anal Toxicol,* 33, 569–577.
18. Gunnar, T., Ariniemi, K., Lillsunde, P., 2005. Validated toxicological determination of 30 drugs of abuse as optimized derivatives in oral fluid by long column fast gas chromatography/electron impact mass spectrometry. *J Mass Spectrom,* 40, 739–753.
19. Kala, S.V., Harris, S.E., Freijo, T.D., Gerlich, S., 2008. Validation of analysis of amphetamines, opiates, phencyclidine, cocaine, and benzoylecgonine in oral fluids by liquid chromatography-tandem mass spectrometry. *J Anal Toxicol,* 32, 605–611.
20. Maurer, H.H., 2005. Advances in analytical toxicology: the current role of liquid chromatography-mass spectrometry in drug quantification in blood and oral fluid. *Anal Bioanal Chem,* 381, 110–118.
21. Ngwa, G., Fritch, D., Blum, K., Newland, G., 2007. Simultaneous analysis of 14 benzodiazepines in oral fluid by solid-phase extraction and LC–MS–MS. *J Anal Toxicol,* 31, 369–376.
22. Oiestad, E.L., Johansen, U., Christophersen, A.S., 2007. Drug screening of preserved oral fluid by liquid chromatography-tandem mass spectrometry. *Clin Chem,* 53, 300–309.
23. Sergi, M., Bafile, E., Compagnone, D., Curini, R., D'Ascenzo, G., Romolo, F.S., 2009. Multiclass analysis of illicit drugs in plasma and oral fluids by LC–MS/MS. *Anal Bioanal Chem,* 393, 709–718.
24. Simoes, S.S., Ajenjo, A.C., Franco, J.M., Vieira, D.N., Dias, M.J., 2009. Liquid chromatography/tandem mass spectrometry for the qualitative and quantitative analysis of illicit drugs and medicines in preserved oral fluid. *Rapid Commun Mass Spectrom,* 23, 1451–1460.
25. Wang, I.T., Feng, Y.T., Chen, C.Y., 2010. Determination of 17 illicit drugs in oral fluid using isotope dilution ultra-high performance liquid chromatography/tandem mass spectrometry with three atmospheric pressure ionizations. *J Chromatogr B Analyt Technol Biomed Life Sci,* 878, 3095–3105.
26. Wood, M., Laloup, M., Ramirez Fernandez, M.M., Jenkins, K.M., Young, M.S., Ramaekers, J.G., De Boeck, G., Samyn, N., 2005. Quantitative analysis of multiple illicit drugs in preserved oral fluid by solid-phase extraction and liquid chromatography-tandem mass spectrometry. *Forensic Sci Int,* 150, 227–238.
27. Wylie, F.M., Torrance, H., Anderson, R.A., Oliver, J.S., 2005. Drugs in oral fluid Part I. Validation of an analytical procedure for licit and illicit drugs in oral fluid. *Forensic Sci Int,* 150, 191–198.
28. Yonamine, M., Tawil, N., Moreau, R.L., Silva, O.A., 2003. Solid-phase micro-extraction-gas chromatography-mass spectrometry and headspace-gas chromatography of tetrahydrocannabinol, amphetamine, methamphetamine, cocaine and ethanol in saliva samples. *J Chromatogr B Analyt Technol Biomed Life Sci,* 789, 73–78.
29. Haeckel, R., 1993. Factors influencing the saliva/plasma ratio of drugs. *Ann N Y Acad Sci,* 694, 128–142.
30. Aps, J.K., Martens, L.C., 2005. Review: The physiology of saliva and transfer of drugs into saliva. *Forensic Sci Int,* 150, 119–131.
31. Tenovuo, J.O., 1989. Human saliva: clinical chemistry and microbiology. Volume 1. Boca Raton: CRC Press, Inc.
32. Samyn, N., Verstraete, A., van Haeren, C., Kintz, P., 1999. Analysis of drugs of abuse in saliva. *Forensic Sci Rev,* 11, 1–19.
33. Rathbone, M.J., 1996. Oral mucosal drug delivery. New York: M. Dekker, Inc.
34. Jusko, W.J., Milsap, R.L., 1993. Pharmacokinetic principles of drug distribution in saliva. *Ann N Y Acad Sci,* 694, 36–47.
35. Jenkins, A.J., Oyler, J.M., Cone, E.J., 1995. Comparison of heroin and cocaine concentrations in saliva with concentrations in blood and plasma. *J Anal Toxicol,* 19, 359–374.
36. Cone, E.J., Oyler, J., Darwin, W.D., 1997. Cocaine disposition in saliva following intravenous, intranasal, and smoked administration. *J Anal Toxicol,* 21, 465–475.
37. Rohrig, T.P., Moore, C., 2003. The determination of morphine in urine and oral fluid following ingestion of poppy seeds. *J Anal Toxicol,* 27, 449–452.
38. Dolan, K., Rouen, D., Kimber, J., 2004. An overview of the use of urine, hair, sweat and saliva to detect drug use. *Drug Alcohol Rev,* 23, 213–217.
39. Quest Diagnostics Incorporated, *Drug Use Among American Workers Declined 74% Over the Past 25 Years, Finds Unprecedented Analysis of More Than 125 Million Workplace Urine Tests, http://blog.employersolutions.com/wp-content/uploads/2013/11/dti25-press-release-11-18-2013.pdf*, 18 November 2013 (accessed 19 August 2014).
40. Cone, E.J., Presley, L., Lehrer, M., Seiter, W., Smith, M., Kardos, K., Fritch, D., Salamone, S., Niedbala, R.S., 2002. Oral fluid testing for drugs of abuse: Positive prevalence rates by Intercept™ immunoassay screening and GC–MS–MS confirmation and suggested cutoff concentrations. *J Anal Toxicol,* 26, 541–546.
41. Heltsley, R., DePriest, A., Black, D.L., Crouch, D.J., Robert, T., Marshall, L., Meadors, V.M., Caplan, Y.H., Cone, E.J., 2012. Oral Fluid Drug Testing of Chronic Pain Patients. II. Comparison of Paired Oral Fluid and Urine Specimens. *J Anal Toxicol,* 36, 75–80.
42. Vindenes, V., Yttredal, B., Oiestad, E.L., Waal, H., Bernard, J.P., Morland, J.G., Christophersen, A.S., 2011. Oral fluid is a viable alternative for monitoring drug abuse: Detection of drugs in oral fluid by liquid chromatography-tandem mass spectrometry and comparison to the results from urine samples from patients treated with methadone or buprenorphine. *J Anal Toxicol,* 35, 32–39.
43. Wish, E.D., Yacoubian, G.S., Jr., 2002. A comparison of the intercept oral specimen collection device to laboratory urinalysis among Baltimore City arrestees. *Fed Probat,* 66, 27–29.
44. Yacoubian, G.S., Jr., Cone, E.J., 2006. A comparison between the Intercept Oral Fluid Collection Device and urinalysis among Baltimore City probationers. *J Crim Justice,* 34, 413–424.
45. Yacoubian, G.S., Jr., Wish, E.D., Perez, D.M., 2001. A comparison of saliva testing to urinalysis in an arrestee population. *J Psychoactive Drugs,* 33, 289–294.
46. Allen, K.R., 2011. Screening for drugs of abuse: which matrix, oral fluid or urine? *Ann Clin Biochem,* 48, 531–541.
47. Henskens, Y.M., van den Keijbus, P.A., Veerman, E.C., Van der Weijden, G.A., Timmerman, M.F., Snoek, C.M., Van der Velden, U., Nieuw Amerongen, A.V., 1996. Protein composition of whole and parotid saliva in healthy and periodontitis subjects. *J Periodontal Res,* 31(1), 57–65.
48. Bibi, G., Green, Y., Nagler, R.M., 2008. Compositional and oxidative analysis in the saliva and serum of predialysis chronic kidney disease patients and end-stage renal failure patients on peritoneal dialysis. *Therapeutic Apheresis and Dialysis,* 12(2), 164–170.
49. Izutsu, K.T., Truelove, E.L., Bleyer, W.A., Anderson, W.M., Schubert, M.M., Rice, J.C., 1981. Whole saliva albumin as an indicator of stomatitis in cancer therapy patients. *Cancer,* 48(6), 1450–1454.
50. Gronblad, E.A., Lindholm,K., 1987. Salivary immunoglobin concentrations in predentate and edentulous mouths. *Scand J Dent Res,* 95(1), 27–31.
51. Mackinnon, L.T., Jenkins, D.G., 1993. Decreased salivary immunoglobulins after intense interval exercise before and after training. *Med Sci Sports Exerc,* 25(6), 678–683.
52. Crouch, D.J., 2005. Oral fluid collection: the neglected variable in oral fluid testing. *Forensic Sci Int,* 150, 165–173.
53. Dickson, S., Park, A., Nolan, S., Kenworthy, S., Nicholson, C., Midgley, J., Pinfold, R., Hampton, S., 2007. The recovery of illicit drugs from oral fluid sampling devices. *Forensic Sci Int,* 165, 78–84.
54. Langel, K., Engblom, C., Pehrsson, A., Gunnar, T., Ariniemi, K., Lillsunde, P., 2008. Drug testing in oral fluid-evaluation of sample collection devices. *J Anal Toxicol,* 32, 393–401.
55. Moore, C., Rana, S., Coulter, C., 2007. Simultaneous identification of 2-carboxy-tetrahydrocannabinol, tetrahydrocannabinol, cannabinol and cannabidiol in oral fluid. *J Chromatogr B Analyt Technol Biomed Life Sci,* 852, 459–464.

56. Moore, C., Vincent, M., Rana, S., Coulter, C., Agrawal, A., Soares, J., 2006. Stability of Delta(9)-tetrahydrocannabinol (THC) in oral fluid using the Quantisal collection device. *Forensic Sci Int,* 164, 126–130.
57. Ventura, M., Pichini, S., Ventura, R., Leal, S., Zuccaro, P., Pacifici, R., de la Torre, R., 2009. Stability of drugs of abuse in oral fluid collection devices with purpose of external quality assessment schemes. *Ther Drug Monit,* 31, 277–280.
58. Niedbala, R.S., Kardos, K.W., Fritch, D.F., Kardos, S., Fries, T., Waga, J., Robb, J., Cone, E.J., 2001. Detection of marijuana use by oral fluid and urine analysis following single-dose administration of smoked and oral marijuana. *J Anal Toxicol,* 25, 289–303.
59. Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings,* NSDUH Series H–46, HHS Publication No. (SMA) 13–4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
60. Substance Abuse and Mental Health Services Administration, *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits.* HHS Publication No. (SMA) 13–4760, DAWN Series D–39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
61. U.S. Drug Enforcement Administration, Office of Diversion Control, 2013. *National Forensic Laboratory Information System: Year 2012 Annual Report.* Springfield, VA: U.S. Drug Enforcement Administration.
62. Cone, E.J., Darwin, W.D., Gorodetzky, C.W., Tan,T., 1978. Comparative metabolism of hydrocodone in man, rat, guinea pig, rabbit, and dog. *Drug Metab Dispos,* 6, 488–493.
63. Poyhia, R., Seppala, T., Olkkola, K.T., Kalso, E., 1992. The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. *Br J Clin Pharmacol,* 33, 617–621.
64. Huestis, M.A., Henningfield, J.E., Cone, E.J., 1992. Blood cannabinoids. I. Absorption of THC and formation of 11–OH–THC and THCCOOH during and after smoking marijuana. *J Anal Toxicol,* 16, 276–282.
65. Perez-Reyes, M., 1990. Marijuana smoking: factors that influence the bioavailability of tetrahydrocannabinol. In: C.N. Chiang & R.L. Hawks (Eds.), Research Findings on Smoking of Abused Substances, NIDA Research Monograph number99, Rockville, pp. 42–62.
66. Milman, G., Schwope, D.M., Schwilke, E.W., Darwin, W.D., Kelly, D.L., Goodwin, R.S., Gorelick, D.A., Huestis, M.A., 2011. Oral Fluid and Plasma Cannabinoid Ratios after Around-the-Clock Controlled Oral {Delta}9-Tetrahydrocannabinol Administration. *Clin Chem,* 57, 1597–1606.
67. Niedbala, R.S., Kardos, K.W., Fritch, E.F., Kunsman, K.P., Blum, K.A., Newland, G.A., Waga, J., Kurtz, L., Bronsgeest, M., Cone, E.J., 2005. Passive cannabis smoke exposure and oral fluid testing. II. Two studies of extreme cannabis smoke exposure in a motor vehicle. *J Anal Toxicol,* 29, 607–615.
68. Huestis, M.A., Cone, E.J., 2004. Relationship of delta-9-tetrahydrocannabinol in oral fluid to plasma after controlled administration of smoked cannabis. *J Anal Toxicol,* 28, 394–399.
69. Kauert, G.F., Ramaekers, J.G., Schneider, E., Moeller, M.R., Toennes, SW., 2007. Pharmacokinetic properties of delta9-tetrahydrocannabinol in serum and oral fluid. *J Anal Toxicol,* 31, 288–293.
70. Ramaekers, J.G., Moeller, M.R., van, R.P., Theunissen, E.L., Schneider, E., Kauert, G., 2006. Cognition and motor control as a function of Delta9–THC concentration in serum and oral fluid: limits of impairment. *Drug Alcohol Depend,* 85, 114–122.
71. Menkes, D.B., Howard, R.C., Spears, G.F.S., Cairns, E.R., 1991. Salivary THC following cannabis smoking correlates with subjective intoxication and heart rate. *Psychopharmacology (Berl),* 103, 277–279.
72. Moore, C., Coulter, C., Rana, S., Vincent, M., Soares, J., 2006. Analytical procedure for the determination of the marijuana metabolite 11-nor-Delta9-tetrahydrocannabinol-9-carboxylic acid in oral fluid specimens. *J Anal Toxicol,* 30, 409–412.
73. Day, D., Kuntz, D.J., Feldman, M., Presley, L., 2006. Detection of THCA in oral fluid by GC–MS–MS. *J Anal Toxicol,* 30, 645–650.
74. Moore, C., Ross, W., Coulter, C., Adams, L., Rana, S., Vincent, M., Soares, J., 2006. Detection of the marijuana metabolite 11-nor-Delta9-tetrahydrocannabinol-9-carboxylic acid in oral fluid specimens and its contribution to positive results in screening assays. *J Anal Toxicol,* 30, 413–418.
75. Moore, C., Rana, S., Coulter, C., Day, D., Vincent, M., Soares, J., 2007. Detection of conjugated 11-nor-Delta9-tetrahydrocannabinol-9-carboxylic acid in oral fluid. *J Anal Toxicol,* 31, 187–194.
76. Lee, D., Milman, G., Barnes, A.J., Goodwin, R.S., Hirvonen, J., Huestis, M.A., 2011. Oral fluid cannabinoids in chronic, daily Cannabis smokers during sustained, monitored abstinence. *Clin Chem,* 57, 1127–1136.
77. Milman, G., Schwope, D.M., Gorelick, D.A., Huestis, M.A., 2012. Cannabinoids and metabolites in expectorated oral fluid following controlled smoked cannabis. *Clin Chim Acta,* 413, 765–770.
78. Lee, D., Schwope, D.M., Milman, G., Barnes, A.J., Gorelick, D.A., Huestis, M.A., 2012. Cannabinoid disposition in oral fluid after controlled smoked cannabis. *Clin Chem,* 58, 748–756.
79. Schwope, D.M., Milman, G., Huestis, M.A., 2010. Validation of an enzyme immunoassay for detection and semiquantification of cannabinoids in oral fluid. *Clin Chem,* 56, 1007–1014.
80. Moore, C., Coulter, C., Uges, D., Tuyay, J., van der Linde, S., van Leeuwen, A., Garnier, M., Orbita, J., Jr., 2011. Cannabinoids in oral fluid following passive exposure to marijuana smoke. *Forensic Sci Int,* 212, 227–230.
81. Sachs, H., Dressler, U., 2000. Detection of THCCOOH in hair by MSD–NCI after HPLC clean-up. *Forensic Sci Int,* 107, 239–247.
82. Anizan, S., Milman, G., Desrosiers.N., Barnes, A.J., Gorelick, D.A., Huestis, M.A., 2013. Oral fluid cannabinoid concentrations following controlled smoked cannabis in chronic frequent and occasional smokers. *Anal Bioanal Chem,* 405, 8451–8461.
83. Niedbala, S., Kardos, K., Salamone, S., Fritch, D., Bronsgeest, M., Cone, E.J., 2004. Passive cannabis smoke exposure and oral fluid testing. *J Anal Toxicol,* 28, 546–552.
84. Milman, G., Barnes, A.J., Lowe, R.H., Huestis, M.A., 2010. Simultaneous quantification of cannabinoids and metabolites in oral fluid by two-dimensional gas chromatography mass spectrometry. *J Chromatogr A,* 1217, 1513–1521.
85. Kim, I., Barnes, A.J., Oyler, J.M., Schepers, R., Joseph, R.E., Jr., Cone, E.J., Lafko, D., Moolchan, E.T., Huestis, M.A., 2002. Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration. *Clin Chem,* 48, 1486–1496.
86. Cone, E.J., Welch, P., Paul, B.D., Mitchell, J.M., 1991. Forensic drug testing for opiates, III. Urinary excretion rates of morphine and codeine following codeine administration. *J Anal Toxicol,* 15, 161–166.
87. O'Neal, C.L., Crouch, D.J., Rollins, D.E., Fatah, A., Cheever, M.L., 1999. Correlation of saliva codeine concentrations with plasma concentrations after oral codeine administration. *J Anal Toxicol,* 23, 452–459.
88. Adler, T.K., Fijimoto, J.M., Way, E.L., Baker, E.M., 1955. The metabolic fate of codeine in man. *J Pharmacol Exp Ther,* 114, 251–262.
89. Cone, E.J., Darwin, W.D., Gorodetzky, C.W., 1979. Comparative metabolism of codeine in man, rat, dog, guinea-pig and rabbit: identification of four new metabolites. *J Pharm Pharmacol,* 31, 314–317.
90. Oyler, J.M., Cone, E.J., Joseph, R.E., Jr., Huestis, M.A., 2000. Identification of hydrocodone in human urine following controlled codeine administration. *J Anal Toxicol,* 24, 530–535.
91. Cone, E.J., 1993. Saliva testing for drugs of abuse. *Ann N Y Acad Sci,* 694, 91–127.
92. Kopecky, E.A., Jacobson, S., Klein, J., Kapur, B., Koren, G., 1997. Correlation of morphine sulfate in blood plasma and saliva in pediatric patients. *Ther Drug Monit,* 19, 530–534.
93. Cone, E.J., 2011. Oral fluid results

compared to self reports of recent cocaine and heroin use by methadone maintenance patients. *Forensic Sci Int,* 215, 88–91.
94. Cone, E.J., Clarke, J., Tsanaclis, L., 2007. Prevalence and disposition of drugs of abuse and opioid treatment drugs in oral fluid. *J Anal Toxicol,* 31, 424–433.
95. Dams, R., Choo, R.E., Lambert, W.E., Jones, H., Huestis, M.A., 2007. Oral fluid as an alternative matrix to monitor opiate and cocaine use in substance-abuse treatment patients. *Drug Alcohol Depend,* 87, 258–267.
96. Presley, L., Lehrer, M., Seiter, W., Hahn, D., Rowland, B., Smith, M., Kardos, K.W., Fritch, D., Salamone, S., Niedbala, R.S., Cone, E.J., 2003. High prevalence of 6-acetylmorphine in morphine-positive oral fluid specimens. *Forensic Sci Int,* 133, 22–25.
97. Cook, C.E., Brine, D.R., Jeffcoat, A.R., Hill, J.M., Wall, M.E., Perez-Reyes, M., DiGuiseppi, S.R., 1982. Phencyclidine disposition after intravenous and oral doses. *Clin Pharmacol Ther,* 31, 625–634.
98. McCarron, M.M., Walberg, C.B., Soares, J.R., Gross, S.J., Baselt, R.C., 1984. Detection of phencyclidine usage by radioimmunoassay of saliva. *J Anal Toxicol,* 8, 197–201.
99. Wan, S.H., Matin, S.B., Azarnoff, D.L., 1978. Kinetics, salivary excretion of amphetamine isomers, and effect of urinary pH. *Clin Pharmacol Ther,* 23, 585–590.
100. Engblom, C., Gunnar, T., Rantanen,A., Lillsunde, P., 2007. Driving under the influence of drugs—amphetamine concentrations in oral fluid and whole blood samples. *J Anal Toxicol,* 31, 276–280.
101. Huestis, M.A., Cone, E.J., 2007. Methamphetamine disposition in oral fluid, plasma, and urine. *Ann N Y Acad Sci,* 1098, 104–121.
102. Schepers, R.J., Oyler, J.M., Joseph, R.E., Jr., Cone, E.J., Moolchan, E.T., Huestis, M.A., 2003. Methamphetamine and amphetamine pharmacokinetics in oral fluid and plasma after controlled oral methamphetamine administration to human volunteers. *Clin Chem,* 49, 121–132.
103. Barnes, A.J., Scheidweiler, K.B., Kolbrich-Spargo, E.A., Gorelick, D.A., Goodwin, R.S., Huestis, M.A., 2011. MDMA and metabolite disposition in expectorated oral fluid after controlled oral MDMA administration. *Ther Drug Monit,* 33, 602–608.
104. Navarro, M., Pichini, S., Farre, M., Ortuno, J., Roset, P.N., Segura, J., de.la Torre, R., 2001. Usefulness of saliva for measurement of 3, 4-methylenedioxymethamphetamine and its metabolites: correlation with plasma drug concentrations and effect of salivary pH. *Clin Chem,* 47, 1788–1795.
105. Samyn, N., De Boeck, G., Wood, M., Lamers, C.T., De Waard, D., Brookhuis, K.A., Verstraete, A.G., Riedel, W.J., 2002. Plasma, oral fluid and sweat wipe ecstasy concentrations in controlled and real life conditions. *Forensic Sci Int,* 128, 90–97.
106. Freudenmann, R.W., Spitzer, M., 2004. The Neuropsychopharmacology and Toxicology of 3, 4-methylenedioxy-N-ethyl-amphetamine (MDEA). *CNS Drug Rev,* 10, 89–116.
107. U.S. Department of Health and Human Services, Behavioral Health Coordinating Committee, Prescription Drug Abuse Subcommittee, *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities.* Department of Health and Human Services, 2013. *http://www.cdc.gov/HomeandRecreationalSafety/pdf/HHS_Prescription_Drug_Abuse_Report_09.2013.pdf* (accessed 15 September 2014).
108. Heltsley, R., DePriest, A., Black, D.L., Robert, T., Marshall, L., Meadors, V.M., Caplan, Y.H., Cone, E.J., 2011. Oral fluid drug testing of chronic pain patients. I. Positive prevalence rates of licit and illicit drugs. *J Anal Toxicol,*35, 529–540.
109. Cone, E.J., Darwin, W.D., Buchwald, W.F., Gorodetzky, C.W., 1983. Oxymorphone metabolism and urinary excretion in human, rat, guinea pig, rabbit, and dog. *Drug Metab Dispos,* 11, 446–450.
110. Ritschel, W., Parab, P.V., Denson, D.D., Coyle, D.E., Gregg, R.V., 1987. Absolute bioavailability of hydromorphone after peroral and rectal administration in humans: saliva/plasma ratio and clinical effects. *J Clin Pharmacol,* 27, 647–653.
111. Cone, E.J., Phelps, B.A., Gorodetzky, C.W., 1977. Urinary excretion of hydromorphone and metabolites in humans, rats, dogs, guinea pigs, and rabbits. *J Pharm Sci,* 66, 1709–1713.
112. Cone, E.J., Caplan, Y.H., Moser, F., Robert, T., Black, D., 2008. Evidence that morphine is metabolized to hydromorphone but not to oxymorphone. *J Anal Toxicol,* 32, 319–323.
113. Cone, E.J., Heit, H.A., Caplan, Y.H., Gourlay, D., 2006. Evidence of morphine metabolism to hydromorphone in pain patients chronically treated with morphine. *J Anal Toxicol,* 30, 1–5.

The Department believes that the benefits of the proposed Mandatory Guidelines using Oral Fluid Specimens outweigh the costs to include this additional specimen type in federal workplace drug testing programs. There is no requirement for federal agencies to use oral fluid as part of their drug testing program. A federal agency may choose to use urine, oral fluid, or both specimen types in their program based on the agency's mission, its employees' duties, and the danger to the public health and safety or to national security that could result from an employee's failure to carry out the duties of his or her position.

Dated: May 4, 2015.

**Pamela S. Hyde,**

*Administrator, SAMHSA.*

Dated: May 7, 2015.

**Sylvia M. Burwell,**

*Secretary.*

For reasons set forth in the preamble, the Department proposes to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include Mandatory Guidelines using Oral Fluid Specimens to read as follows:

## Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid Specimens

### Subpart A—Applicability

1.1 To whom do these Guidelines apply?
1.2 Who is responsible for developing and implementing these Guidelines?
1.3 How does a federal agency request a change from these Guidelines?
1.4 How are these Guidelines revised?
1.5 What do the terms used in these Guidelines mean?
1.6 What is an agency required to do to protect employee records?
1.7 What is a refusal to take a federally regulated drug test?
1.8 What are the potential consequences for refusing to take a federally regulated drug test?

### Subpart B—Oral Fluid Specimens

2.1 What type of specimen may be collected?
2.2 Under what circumstances may an oral fluid specimen be collected?
2.3 How is each oral fluid specimen collected?
2.4 What volume of oral fluid is collected?
2.5 How is the split oral fluid specimen collected?
2.6 When may an entity or individual release an oral fluid specimen?

### Subpart C—Oral Fluid Specimen Tests

3.1 Which tests are conducted on an oral fluid specimen?
3.2 May a specimen be tested for additional drugs?
3.3 May any of the specimens be used for other purposes?
3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?
3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?
3.6 What criteria are used to report an oral fluid specimen as adulterated?
3.7 What criteria are used to report an invalid result for an oral fluid specimen?

### Subpart D—Collectors

4.1 Who may collect a specimen?
4.2 Who may not collect a specimen?
4.3 What are the requirements to be a collector?
4.4 What are the requirements to be a trainer for collectors?
4.5 What must a federal agency do before a

collector is permitted to collect a specimen?

**Subpart E—Collection Sites**

5.1 Where can a collection for a drug test take place?
5.2 What are the requirements for a collection site?
5.3 Where must collection site records be stored?
5.4 How long must collection site records be stored?
5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
5.6 What are the privacy requirements when collecting an oral fluid specimen?

**Subpart F—Federal Drug Testing Custody and Control Form**

6.1 What federal form is used to document custody and control?
6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

**Subpart G—Oral Fluid Specimen Collection Devices**

7.1 What is used to collect an oral fluid specimen?
7.2 What are the requirements for an oral fluid collection device?
7.3 What are the minimum performance requirements for a collection device?

**Subpart H—Oral Fluid Specimen Collection Procedure**

8.1 What privacy must the donor be given when providing an oral fluid specimen?
8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?
8.3 What are the preliminary steps in the oral fluid specimen collection procedure?
8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?
8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?
8.6 What procedure is used when the donor states that he or she is unable to provide an oral fluid specimen?
8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?
8.8 How does the collector prepare the oral fluid specimens?
8.9 How does the collector report a donor's refusal to test?
8.10 What are a federal agency's responsibilities for a collection site?

**Subpart I—HHS Certification of Laboratories**

9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?
9.2 What is the process for a laboratory to become HHS-certified?
9.3 What is the process for a laboratory to maintain HHS certification?
9.4 What is the process when a laboratory does not maintain its HHS certification?
9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?
9.6 What are the PT requirements for an applicant laboratory?
9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?
9.8 What are the inspection requirements for an applicant laboratory?
9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?
9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?
9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?
9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?
9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?
9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?
9.17 Where is the list of HHS-certified laboratories published?

**Subpart J—Blind Samples Submitted by an Agency**

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?
10.2 What are the requirements for blind samples?
10.3 How is a blind sample submitted to an HHS-certified laboratory?
10.4 What happens if an inconsistent result is reported for a blind sample?

**Subpart K—Laboratory**

11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?
11.2 What are the responsibilities of the responsible person (RP)?
11.3 What scientific qualifications must the RP have?
11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?
11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?
11.7 What security measures must an HHS-certified laboratory maintain?
11.8 What are the laboratory chain of custody requirements for specimens and aliquots?
11.9 What are the requirements for an initial drug test?
11.10 What must an HHS-certified laboratory do to validate an initial drug test?
11.11 What are the batch quality control requirements when conducting an initial drug test?
11.12 What are the requirements for a confirmatory drug test?
11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?
11.14 What are the batch quality control requirements when conducting a confirmatory drug test?
11.15 What are the analytical and quality control requirements for conducting specimen validity tests?
11.16 What must an HHS-certified laboratory do to validate a specimen validity test?
11.17 What are the requirements for an HHS-certified laboratory to report a test result?
11.18 How long must an HHS-certified laboratory retain specimens?
11.19 How long must an HHS-certified laboratory retain records?
11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?
11.21 What HHS-certified laboratory information is available to a federal agency?
11.22 What HHS-certified laboratory information is available to a federal employee?
11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

**Subpart L—Instrumented Initial Test Facility (IITF)**

12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

**Subpart M—Medical Review Officer (MRO)**

13.1 Who may serve as an MRO?
13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?
13.3 What training is required before a physician may serve as an MRO?
13.4 What are the responsibilities of an MRO?
13.5 What must an MRO do when reviewing an oral fluid specimen's test results?
13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?
13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?
13.8 Who may request a test of a split (B) specimen?
13.9 How does an MRO report a primary (A) specimen test result to an agency?
13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

**Subpart N—Split Specimen Tests**

14.1 When may a split (B) specimen be tested?
14.2 How does an HHS-certified laboratory test a split (B) specimen when the

primary (A) specimen was reported positive?
14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?
14.4 Who receives the split (B) specimen result?
14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?
14.6 How does an MRO report a split (B) specimen test result to an agency?
14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

**Subpart O—Criteria for Rejecting a Specimen for Testing**

15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?
15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?
15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?
15.4 What discrepancies may require an MRO to cancel a test?

**Subpart P—Laboratory Suspension/ Revocation Procedures**

16.1 When may the HHS certification of a laboratory be suspended?
16.2 What definitions are used for this subpart?
16.3 Are there any limitations on issues subject to review?
16.4 Who represents the parties?
16.5 When must a request for informal review be submitted?
16.6 What is an abeyance agreement?
16.7 What procedures are used to prepare the review file and written argument?
16.8 When is there an opportunity for oral presentation?
16.9 Are there expedited procedures for review of immediate suspension?
16.10 Are any types of communications prohibited?
16.11 How are communications transmitted by the reviewing official?
16.12 What are the authority and responsibilities of the reviewing official?
16.13 What administrative records are maintained?
16.14 What are the requirements for a written decision?
16.15 Is there a review of the final administrative action?

## Subpart A—Applicability

*Section 1.1 To whom do these Guidelines apply?*

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.[1]

*Section 1.2 Who is responsible for developing and implementing these Guidelines?*

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

*Section 1.3 How does a federal agency request a change from these Guidelines?*

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

*Section 1.4 How are these Guidelines revised?*

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) The changes will be published in final as a notice in the **Federal Register**.

*Section 1.5 What do the terms used in these Guidelines mean?*

The following definitions are adopted:

*Accessioner.* The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

*Adulterated Specimen.* A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

*Aliquot.* A portion of a specimen used for testing.

*Alternate Responsible Person.* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

*Alternate Technology Initial Drug Test.* An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

*Batch.* A number of specimens or aliquots handled concurrently as a group.

*Biomarker.* An endogenous substance used to validate a biological specimen.

*Blind Sample.* A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

*Calibrator.* A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

*Cancelled Test.* The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR Part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

Although HHC has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that ''incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988 and any amendments to those guidelines . . .'' See, *e.g.,* 49 U.S.C. § 20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR § 40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

*Carryover.* The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

*Certifying Scientist (CS).* The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

*Certifying Technician (CT).* The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

*Chain of Custody (COC) Procedures.* Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

*Chain of Custody Documents.* Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

*Collection Device.* A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

*Collection Site.* The location where specimens are collected.

*Collector.* A person trained to instruct and assist a donor in providing a specimen.

*Confirmatory Drug Test.* A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

*Confirmatory Specimen Validity Test.* A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

*Control.* A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

*Cutoff.* The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

*Donor.* The individual from whom a specimen is collected.

*Failed to Reconfirm.* The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

*Federal Drug Testing Custody and Control Form (Federal CCF).* The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

*HHS.* The Department of Health and Human Services.

*Initial Drug Test.* An analysis used to differentiate negative specimens from those requiring further testing.

*Initial Specimen Validity Test.* The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

*Instrumented Initial Test Facility (IITF).* A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

*Invalid Result.* The result reported by an HHS-certified laboratory when the laboratory determines that it cannot complete testing or obtain a valid drug test result.

*Laboratory.* A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

*Limit of Detection.* The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

*Limit of Quantification.* For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

*Lot.* A number of units of an item (*e.g.,* reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

*Medical Review Officer (MRO).* A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

*Negative Result.* The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

*Non-Medical Use of a Drug. The use of a prescription drug, whether obtained by prescription or otherwise, other than in the manner or for the time period prescribed, or by a person for whom the drug was not prescribed.*

*Oral Fluid Specimen.* An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

*Oxidizing Adulterant.* A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

*Performance Testing (PT) Sample.* A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

*Positive Result.* The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmation cutoff concentration.

*Reconfirmed.* The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

*Rejected for Testing.* The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2)

*Responsible Person (RP).* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

*Sample.* A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

*Secretary.* The Secretary of the U.S. Department of Health and Human Services.

*Specimen.* A sample collected from a donor at the collection site for the purpose of a drug test.

*Split Specimen Collection (for Oral Fluid).* A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor.

*Standard.* Reference material of known purity or a solution containing a

reference material at a known concentration.

*Section 1.6 What is an agency required to do to protect employee records?*

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, is applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *http://www.hhs.gov/ocr/hipaa*.

*Section 1.7 What is a refusal to take a federally regulated drug test?*

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(4) Fail or decline to participate in an alternate specimen collection (*e.g.,* urine) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(5) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(6) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process); or

(7) Admit to the collector or MRO that you have adulterated or (for urine) substituted the specimen.

*Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?*

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, the collector must terminate that portion of the collection process and take action as described in Section 8.9: immediately notify the federal agency's designated representative by any means (*e.g.,* telephone or secure fax machine) that ensures that the refusal notification is immediately received, document the refusal on the Federal CCF, sign and date the Federal CCF, and send all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

**Subpart B—Oral Fluid Specimens**

*Section 2.1 What type of specimen may be collected?*

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

*Section 2.2 Under what circumstances may an oral fluid specimen be collected?*

A federal agency may collect an oral fluid specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post-accident test;

(e) Return to duty test; or

(f) Follow-up test.

*Section 2.3 How is each oral fluid specimen collected?*

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Section 2.5.

*Section 2.4 What volume of oral fluid is collected?*

A known volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device.

*Section 2.5 How is the split oral fluid specimen collected?*

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* as described in Section 8.8.)

*Section 2.6 When may an entity or individual release an oral fluid specimen?*

Entities and individuals subject to these Guidelines under Section 1.1, may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71 and these Guidelines, to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

**Subpart C—Oral Fluid Drug and Specimen Validity Tests**

*Section 3.1 Which tests are conducted on an oral fluid specimen?*

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided under Section 3.4;

(b) Is authorized to test each specimen for opiates, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each oral fluid specimen:

(1) Determine the albumin concentration on every specimen; or

(2) Determine the immunoglobulin G (IgG) concentration on every specimen.

(d) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

*Section 3.2 May a specimen be tested for additional drugs?*

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

*Section 3.3 May any of the specimens be used for other purposes?*

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies, specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

*Section 3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?*

| Initial test analyte | Initial test cutoff (ng/mL) | Confirmatory test analyte | Confirmatory test cutoff concentration (ng/mL) |
|---|---|---|---|
| Marijuana (THC) [1] | 4 | THC | 2 |
| Cocaine/Benzoylecgonine | [2] 15 | Cocaine | 8 |
| | | Benzoylecgonine | 8 |
| Codeine/Morphine | [2] 30 | Codeine | 15 |
| | | Morphine | 15 |
| Hydrocodone/Hydromorphone | [2] 30 | Hydrocodone | 15 |
| | | Hydromorphone | 15 |
| Oxycodone/Oxymorphone | [2] 30 | Oxycodone | 15 |
| | | Oxymorphone | 15 |
| 6-Acetylmorphine | 3 | 6-Acetylmorphine | 2 |
| Phencyclidine | 3 | Phencyclidine | 2 |
| Amphetamine/Methamphetamine | [2] 25 | Amphetamine | 15 |
| | | Methamphetamine | 15 |
| MDMA [4]/MDA [5]/MDEA [6] | [2] 25 | [3] MDMA | 15 |
| | | [4] MDA | 15 |
| | | [5] MDEA | 15 |

[1] Δ-9-Tetrahydrocannabinol (THC).

[2] *Immunoassay:* The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

*Alternate technology:* Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[3] Methylenedioxymethamphetamine (MDMA).

[4] Methylenedioxyamphetamine (MDA).

[5] Methylenedioxyethylamphetamine (MDEA).

*Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?*

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests as necessary to provide information that the MRO would use to report a verified drug test result [*e.g.,* d, l-stereoisomers determination for methamphetamine, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA), and additional specimen validity tests including adulterants]. All tests must meet appropriate validation and quality control requirements.

*Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?*

An HHS-certified laboratory reports an oral fluid specimen as adulterated

when the presence of an adulterant is verified using an initial test on a first aliquot and a different confirmatory test on a second aliquot.

*Section 3.7 What criteria are used to report an invalid result for an oral fluid specimen?*

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

(a) The albumin concentration is less than 0.6 mg/dL for both the initial (first) test and the second test on two separate aliquots;

(b) The IgG concentration is less than 0.5 mg/L for both the initial (first) test and the second test on two separate aliquots;

(c) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial drug test results cannot be obtained);

(d) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(e) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(f) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(g) The concentration of a biomarker other than albumin or IgG is not consistent with that established for human oral fluid.

**Subpart D—Collectors**

*Section 4.1 Who may collect a specimen?*

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

*Section 4.2 Who may not collect a specimen?*

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect his or her own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

*Section 4.3 What are the requirements to be a collector?*

(a) An individual may serve as a collector if he or she fulfills the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen collection device tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are ''error-free.''

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until his or her training as a collector has been properly documented.

*Section 4.4 What are the requirements to be a trainer for collectors?*

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

*Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?*

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

**Subpart E—Collection Sites**

*Section 5.1 Where can a collection for a drug test take place?*

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident

investigation), another site may be used for the collection, providing the collection is performed by a trained oral fluid specimen collector.

*Section 5.2 What are the requirements for a collection site?*

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies; and

(f) The ability to store records securely.

*Section 5.3 Where must collection site records be stored?*

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

*Section 5.4 How long must collection site records be stored?*

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

*Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?*

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering.

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

*Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?*

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

**Subpart F—Federal Drug Testing Custody and Control Form**

*Section 6.1 What federal form is used to document custody and control?*

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

*Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used for an oral fluid specimen?*

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector uses an incorrect form, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that an incorrect form was used by the collector, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the HHS-certified laboratory must wait at least 5 business days before the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test.

**Subpart G—Oral Fluid Specimen Collection Devices**

*Section 7.1 What is used to collect an oral fluid specimen?*

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

*Section 7.2 What are the requirements for an oral fluid collection device?*

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites;

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

*Section 7.3 What are the minimum performance requirements for a collection device?*

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable and reproducible collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be within 0.1 ml of the target volume, and

(2) The volume of diluent in the device should be within 0.05 ml of the diluent target volume;

(c) Stability (recoverable concentrations ≥90 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for one week at room temperature (18–25 °C) and under intended shipping and storage conditions; and

(d) Recover ≥90 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff (see Section 3.4).

**Subpart H—Oral Fluid Specimen Collection Procedure**

*Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?*

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

*Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?*

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

*Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?*

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector requests that the donor opens his or her mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, tobacco, dental retainer).

(1) At this time, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in Section 8.5.

(2) If the donor's mouth is not free of any items that could impede or interfere with the collection of an oral fluid specimen immediately prior to collection, or the donor claims to be a tobacco user, or claims to have ''dry mouth,'' the donor may drink while rinsing his or her mouth with water (up to 4 oz.) and wait 10 minutes before beginning the specimen collection.

(e) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(f) The collector explains the basic collection procedure to the donor.

(g) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(h) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

*Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?*

(a) The collector will provide or the donor may select a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The specimen collection device will be opened in view of the donor.

(1) Both the donor and the collector must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(b) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(1) The collector may set a reasonable time limit for specimen collection (based on the device used, not to exceed 15 minutes per device).

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen, the collector must note the conduct on the Federal CCF.

*Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?*

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for placing the specimen collection device in his or her mouth. The collector must ensure the collection is performed correctly and that the collection device is working properly. If the device fails to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and a new Federal CCF.

(2) The donor and collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to provide a second specimen as required in step (a)(1) above, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

*Section 8.6 What procedure is used when the donor states that he or she is unable to provide an oral fluid specimen?*

(a) If the donor states that he or she is unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates his or her inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that he or she could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor is not required to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that he or she is unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid

specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

*Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?*

No, unless the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

*Section 8.8 How does the collector prepare the oral fluid specimens?*

(a) All federal agency collections are to be split specimen collections.

An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF; or

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes.

(b) A known volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube A'' and a known volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from him or her. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints his or her name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen. The collector must also send a copy of the Federal CCF to the HHS-certified laboratory.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

*Section 8.9 How does the collector report a donor's refusal to test?*

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

*Section 8.10 What are a federal agency's responsibilities for a collection site?*

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

**Subpart I—HHS Certification of Laboratories**

*Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?*

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

*Section 9.2 What is the process for a laboratory to become HHS-certified?*

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

*Section 9.3 What is the process for a laboratory to maintain HHS certification?*

(a) To maintain HHS certification, a laboratory must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

*Section 9.4 What is the process when a laboratory does not maintain its HHS certification?*

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.7;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

*Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?*

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be less than 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to the following criteria:

(1) The concentration of albumin and/or IgG will be at least 20 percent below the cutoff; or

(2) The concentration of albumin and/or IgG may be another concentration for a special purpose.

(c) The laboratory must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

*Section 9.6 What are the PT requirements for an applicant laboratory?*

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Albumin concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) IgG values are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(b) Failure to satisfy these requirements will result in disqualification.

*Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?*

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ±50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each

individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Albumin concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) IgG values are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

*Section 9.8 What are the inspection requirements for an applicant laboratory?*

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

*Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?*

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

*Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?*

(a) An individual may be selected as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either an HHS-certified laboratory responsible person or certifying scientist as described in Subpart K;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

(b) The Secretary or a federal agency may conduct an inspection at any time.

*Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?*

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

*Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?*

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

*Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?*

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory by a federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

*Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?*

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

*Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?*

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

*Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?*

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

*Section 9.17 Where is the list of HHS-certified laboratories published?*

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notice is also available on the Internet at *http://www.samhsa.gov/workplace*.

(b) An applicant laboratory is not included on the list.

**Subpart J—Blind Samples Submitted by an Agency**

*Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?*

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

*Section 10.2 What are the requirements for blind samples?*

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

*Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?*

(a) A blind sample must be submitted in the collection device with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

*Section 10.4 What happens if an inconsistent result is reported for a blind sample?*

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

**Subpart K—Laboratory**

*Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?*

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;
(2) Accessioning;
(3) Security;
(4) Quality control/quality assurance programs;
(5) Analytical methods and procedures;
(6) Equipment and maintenance programs;
(7) Personnel training;
(8) Reporting procedures; and
(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

*Section 11.2 What are the responsibilities of the responsible person (RP)?*

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

*Section 11.3 What scientific qualifications must the RP have?*

The RP must have documented scientific qualifications in analytical toxicology. Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

*Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?*

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

*Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?*

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

*Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?*

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with federally regulated specimens. All training must be documented.

*Section 11.7 What security measures must an HHS-certified laboratory maintain?*

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

*Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?*

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

*Section 11.9 What are the requirements for an initial drug test?*

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

*Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?*

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

*Section 11.11 What are the batch quality control requirements when conducting an initial drug test?*

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

*Section 11.12 What are the requirements for a confirmatory drug test?*

(a) The analytical method must use mass spectrometric identification [*e.g.,* gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

*Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?*

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

*Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?*

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

*Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?*

(a) Each specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

*Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?*

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

*Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?*

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(4) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) through (e)(4) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(e) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of Tubes A and B are clearly different (note: A is tested);

(5) The albumin concentration is less than 0.6 mg/dL for both the initial (first) test and the second test on two separate aliquots;

(6) The IgG concentration is less than 0.5 mg/L for both the initial (first) test and the second test on two separate aliquots; or

(7) The concentration of a biomarker other than albumin or IgG is not consistent with that established for human oral fluid.

(f) An HHS-certified laboratory shall reject a primary (A) oral fluid specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all positive, adulterated, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(m) For positive, adulterated, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 11.18 How long must an HHS-certified laboratory retain specimens?*

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (−20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

*Section 11.19 How long must an HHS-certified laboratory retain records?*

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

*Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?*

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated; and

(13) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

*Section 11.21 What HHS-certified laboratory information is available to a federal agency?*

(a) Following a federal agency's receipt of a positive or adulterated drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

*Section 11.22 What HHS-certified laboratory information is available to a federal employee?*

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and the federal agency requesting copies of any records relating to his or her drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

*Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?*

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

**Subpart L—Instrumented Initial Test Facility (IITF)**

*Section 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?*

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

**Subpart M—Medical Review Officer (MRO)**

*Section 13.1 Who may serve as an MRO?*

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs and nonmedical use of prescription drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

*Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?*

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify and/or train physicians as MROs for federal workplace drug testing programs must submit their qualifications and, if

applicable, a sample examination. Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, the course syllabus and materials, documentation that the continuing education courses are accredited by a professional organization, and, if applicable, the delivery method and content of the examination. Each approved MRO training/certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at *http://www.samhsa.gov/workplace/drug-testing.*

*Section 13.3 What training is required before a physician may serve as an MRO?*

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types;

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations), and reporting of results specified by any federal agency for which the individual may serve as an MRO; and

(6) Training in Substance Abuse including information about how to discuss substance misuse and abuse, and how individuals that test positive can access services.

(b) Nationally recognized entities or subspecialty boards that train or certify physicians as MROs should make the MROs aware of prevention and treatment opportunities for individuals after testing positive.

*Section 13.4 What are the responsibilities of an MRO?*

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

*Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?*

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive or adulterated result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL and no legitimate medical explanation: the MRO must determine if there is clinical evidence of illegal use (in addition to the drug test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency.

(ii) For codeine and/or morphine at or above 150 ng/mL and no legitimate medical explanation: the MRO reports a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication), the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in Section 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO

reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine).

(f) When the HHS-certified laboratory reports a rejected for testing result on the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

*Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?*

(a) When another specimen type (*e.g.,* urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

*Section 13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?*

(a) This section concerns a situation in which the donor has a medical condition that precludes him or her from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the

federal agency is not authorized to allow the donor to begin or resume performing official functions because a negative test is needed for that purpose).

*Section 13.8 Who may request a test of a split (B) specimen?*

(a) For a positive or adulterated result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that he or she has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

*Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?*

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

*Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?*

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

**Subpart N—Split Specimen Tests**

*Section 14.1 When may a split (B) specimen be tested?*

(a) The donor may verbally request through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the verbal request after being informed of the result by the MRO. The MRO must document in his or her records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

*Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?*

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

*Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?*

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

*Section 14.4 Who receives the split (B) specimen result?*

The second HHS-certified laboratory must report the result to the MRO.

*Section 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?*

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split oral fluid specimen as:

(a) *Reconfirmed the drug(s) or adulteration result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and not adulterated.* The MRO reports to the agency a failed to reconfirm result specify drug(s)], cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(d) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and gives the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the

agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated.* The MRO reports a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the Drug-free Workplace Program regarding the test results for the specimen.

(h) *Failed to reconfirm adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterant.* The MRO reports to the agency a reconfirmed result (specify adulterant) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated) although Laboratory B failed to reconfirm the drug(s) result.

(j) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterant.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and adulterant] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm at least one drug and reconfirmed the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s) and adulterant] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the reconfirmed adulterant although Laboratory B failed to reconfirm one or more drugs.

(l) *Failed to reconfirm at least one drug and failed to reconfirm the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s) and adulterant]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterant.

*Section 14.6 How does an MRO report a split (B) specimen test result to an agency?*

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

*Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?*

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

**Subpart O—Criteria for Rejecting a Specimen for Testing**

*Section 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?*

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen; or

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen.

*Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?*

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all

the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

*Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?*

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory are considered insignificant and should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's SSN;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) A ''specimen collection'' box is not marked;

(11) The lot number of the collection device used for the collection is missing;

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist or certifying technician fails to print his or her name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

*Section 15.4 What discrepancies may require an MRO to cancel a test?*

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified oral fluid laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

**Subpart P—Laboratory Suspension/Revocation Procedures**

*Section 16.1 When may the HHS certification of a laboratory be suspended?*

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

*Section 16.2 What definitions are used for this subpart?*

*Appellant.* Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

*Respondent.* Means the person or persons designated by the Secretary in implementing these Guidelines.

*Reviewing Official.* Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

*Section 16.3 Are there any limitations on issues subject to review?*

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

*Section 16.4 Who represents the parties?*

The appellant's request for review shall specify the name, address, and

telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

*Section 16.5 When must a request for informal review be submitted?*

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

*Section 16.6 What is an abeyance agreement?*

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

*Section 16.7 What procedures are used to prepare the review file and written argument?*

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

*Section 16.8 When is there an opportunity for oral presentation?*

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the

parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

*Section 16.9 Are there expedited procedures for review of immediate suspension?*

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

*Section 16.10 Are any types of communications prohibited?*

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

*Section 16.11 How are communications transmitted by the reviewing official?*

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

*Section 16.12 What are the authority and responsibilities of the reviewing official?*

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

*Section 16.13 What administrative records are maintained?*

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

*Section 16.14 What are the requirements for a written decision?*

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The

decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

*Section 16.15 Is there a review of the final administrative action?*

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. 2015–11523 Filed 5–13–15; 4:15 pm]

BILLING CODE 4162–20–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Mandatory Guidelines for Federal Workplace Drug Testing Programs

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Notice of proposed revisions to the mandatory guidelines by the Secretary of Health and Human Services.

**SUMMARY:** The Department of Health and Human Services (''HHS'' or ''Department'') is proposing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines), 73 FR 71858 (November 25, 2008) for urine testing.

**DATES:** Submit comments on or before July 14, 2015.

**ADDRESSES:** In commenting, please refer to file code SAMHSA–2015–0002. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow ''Submit a comment'' instructions.
- *By regular mail.* You may mail written comments to the following address ONLY: SAMHSA, Attention Division of Workplace Programs (DWP), 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: SAMHSA, Attention DWP, 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20850.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: SAMHSA, Attention DWP, 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20850. If you intend to deliver your comments to the Rockville address, call telephone number (240) 276–2600 in advance to schedule your arrival with one of our staff members. Because access to the interior of the SAMHSA Building is not readily available to persons without federal government identification, commenters are encouraged to schedule their delivery or to leave comments with the security guard front desk located in the main lobby of the building. Comments erroneously mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:** Charles LoDico, M.S., DABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 1 Choke Cherry Road, Room 7–1045, Rockville, MD 20857, telephone (240) 276–2600, fax (240) 276–2610, or email at *charles.lodico@samhsa.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**Executive Summary**

This notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) will revise the initial and confirmatory drug test analytes and methods for urine testing, revise the cutoff for reporting a specimen as adulterated based on low pH, revise the requalification requirements for individuals serving as Medical Review Officers (MROs) and, where appropriate, include references to the use of an alternate specimen in federal workplace drug testing programs. References to an alternate specimen are not applicable until final Guidelines are implemented for the use of the alternative specimen matrix. The Department is issuing a separate Notice in the **Federal Register** proposing Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) to allow federal agencies to collect and test oral fluid specimens in their workplace drug testing programs.

In particular, these revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) allow federal executive branch agencies to test for additional Schedule II of the Controlled Substances Act prescription medications (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in federal drug-free workplace programs, add methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes, raise the lower pH cutoff from 3 to 4 for identifying specimens as adulterated, require MRO requalification training and re-examination at least every five years after initial MRO certification, and allow federal agencies to authorize collection of an alternate specimen (*e.g.,* oral fluid) when a donor in their program is unable to provide a sufficient amount of urine specimen at the collection site. Many of the proposed wording changes and reorganization of the UrMG were made for clarity, to use current scientific terminology or preferred grammar, and for consistency with the proposed OFMG.

**Costs and Benefits**

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. HHS projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens once the proposed OFMG have been

implemented. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and number of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analyte(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

For the added opiate analytes, the two immunoassays currently used for oxycodone and oxymorphone meet the requirements, and two of the three existing opiate immunoassays used in certified laboratories meet the requirements for hydrocodone and hydromorphone analysis. The opiate immunoassay that does not have sufficient cross-reactivity would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, hydromorphone, is used to establish a decision point.

For amphetamines, one of the three existing methylenedioxymeth amphetamine (MDMA) immunoassays used in certified laboratories meets the requirements. The remaining two exhibit insufficient cross-reactivity for MDA. These two immunoassays would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, MDA, is used to establish a decision point. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal because the Department has determined that all HHS certified laboratories testing specimens from federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA and MDEA since the current immunoassays can be adapted to test for these analytes. Laboratory personnel are currently trained and test methods have been implemented. However, there will be some administrative costs associated with adding these analytes. Prior to being allowed to test regulated specimens for these compounds, HHS certified laboratories will be required to demonstrate that their performance meets Guideline requirements by testing three (3) groups of PT samples. The Department will provide the PT samples through the National Laboratory Certification Program (NLCP) at no cost to the certified laboratories. Based on costs charged for specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each of the certified laboratories.

Once the testing has been implemented, the cost per specimen for initial testing for the added analytes will range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported as positive due to costs of sample preparation and analysis. Based on information from non-regulated workplace drug testing for these analytes in 2012 and testing performed by the Department on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen. This would indicate that the total cost per specimen submitted for testing will increase by $0.11–$0.30.

The addition of the Schedule II prescription medications will require MRO review to verify legitimate drug use. Based on the positivity rates from non-regulated workplace drug testing for these analytes and this additional review of specimens confirmed positive for prescription medications, MRO costs are estimated to increase by approximately 3%.

The additional costs for testing and MRO review will be incorporated into the overall cost for the federal agency submitting the specimen to the laboratory. The estimation of costs incurred is based upon overall cost to the federal agency because cost is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Agencies may also incur some costs for training of federal employees such as drug program coordinators due to implementation of the revised Guidelines. However, costs are expected to be minimal in the training process to understand the required changes in these Guidelines.

Based on the current figures, the cost for urine testing in the first year is estimated on 139,500 urine specimens for HHS, 5,820,000 urine specimens for DOT, and 186,000 urine specimens for NRC. Estimated costs are $99,045–$230,175 for HHS, $4,132,200–$9,603,000 for DOT, and $132,060–$306,900 for NRC.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public. Please note that all comments are posted in their entirety, including personal or confidential business information that is included in a comment. SAMHSA posts all comments before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on the Web site to view public comments. Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry RD., Rockville, MD, 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (240) 276–2600.

## Background

The Department of Health and Human Services (HHS), by the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, has established the scientific and technical guidelines for federal workplace drug testing programs and established standards for certification of laboratories engaged in urine drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644],

and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

**History and Proposed Changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs**

At the July 2011 meeting of SAMHSA's Drug Testing Advisory Board (DTAB), Board members voted unanimously for the following:

(1) Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs; and (2) DTAB recommends the inclusion of additional Schedule II prescription medications (*e.g.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

At the January 2012 DTAB meeting, the SAMHSA Administrator received the DTAB recommendations from the July 2011 meeting.

The responses to the April 13, 2004 notice proposing alternative specimen matrices (69 FR 19673) had made it clear that if the Department were to subsequently authorize alternative specimens for the Mandatory Guidelines for Federal Workplace Drug Testing Programs, separate Guidelines would be needed to provide clear and comprehensive information on the scientific and technical requirements for each specimen matrix. Therefore, HHS is proposing Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine (UrMG) and Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid (OFMG). The proposed UrMG and OFMG have been organized into analogous sections and use the same language where possible. The only differences are due to requirements that are specific for each specimen matrix.

Since the original Guidelines were published in 1988, a number of recommendations have been made for additional drugs to be included in federal workplace drug testing programs. Further, the Department monitors drug abuse trends and reviews information on new drugs of abuse from sources such as federal regulators, researchers, the drug testing industry, and public and private sector employers. The Department revised the Guidelines to include 6-acetylmorphine in 1998 (63 FR 63483) and three amphetamine analogues [methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)] in 2008 (73 FR 71858). The July 21, 2011 DTAB recommendations for the added drugs were based on the Board members' review of scientific information on the methods necessary to detect the analytes of these drugs and on drug abuse trends.

The DTAB recommendations, current drug abuse trends and other relevant information, and the private sector experience have led the Department to conclude that the additional opiates oxycodone, oxymorphone, hydrocodone, and hydromorphone should be added in the federal program.

**Provisions for the Administration of the National Laboratory Certification Program (NLCP)**

In accordance with the current practice, an HHS contractor will perform certain functions on behalf of the Department. These functions include maintaining laboratory inspection and performance testing (PT) programs that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Department regarding certification or suspension/revocation of laboratories' certification. It is important to note that, although a contractor gathers and evaluates information provided by the inspectors or laboratories, all final decisions regarding laboratory certification, suspension, or revocation of certification are made by the Secretary.

The Department contributes funds to this contract for purposes not directly related to laboratory certification activities, such as evaluating technologies and instruments and providing assessments of their potential applicability to workplace drug testing programs.

**Organization of Proposed Guidelines**

This preamble describes the differences between the current Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens (UrMG), and the rationale for the differences. In addition, the Preamble presents two topics of special interest to be addressed for the revised Guidelines. These topics are presented first in summary as they appear in the text of the proposed UrMG and later as topics of special interest for which the Department is seeking public comments.

**Subpart A—Applicability**

Section 1.5 defines terms used in the UrMG. Where possible, the Department proposes to revise the definitions in the current Guidelines to apply to any specimen matrix allowed in federal workplace drug testing programs, so the terms and their definitions will be identical in both the UrMG and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens (OFMG). In addition, the Department proposes to add new definitions or revise the definitions in the current Guidelines as needed for terms that apply only to urine (*e.g.,* collection container). The Department also proposes to revise and update terms and definitions in the current Guidelines for clarity and consistency with current scientific terminology (*e.g.,* changing the term limit of quantitation to limit of quantification; no longer using the term quality control samples for both calibrators and controls).

Sections 1.6, 1.7, and 1.8 contain the same policies as described in the current Guidelines with regard to what an agency is required to do to protect employee records, the conditions that constitute refusal to take a federally regulated drug test, and the consequences of a refusal to take a federally regulated drug test. In the proposed UrMG, Section 1.7 of the current Guidelines was divided into two sections for clarity: Section 1.7 describes what constitutes a refusal to test and Section 1.8 describes the subsequent actions and consequences. Section 1.7 also has been reworded as needed to address other authorized specimen types.

**Subpart B—Urine Specimen**

The Department proposes to revise Section 2.1 of the current Guidelines to reflect the Department's proposed expansion of the drug-testing program for federal agencies to permit the use of oral fluid specimens. There is no requirement for federal agencies to use oral fluid as part of their program. When the OFMG become effective and HHS has certified laboratories under the OFMG, a federal agency may choose to use urine, oral fluid, or both specimen types in their drug testing program. Any agency choosing to use urine is required to follow the UrMG and any agency choosing to use oral fluid is required to follow the OFMG. For example, an agency program can randomly assign

individuals to either urine or OF testing, for random or pre-employment testing. This would not only help reduce subversion, but would allow comparison of urine and OF testing outcomes for planning purposes.

Section 2.6 was added to clarify that all entities and individuals identified in Section 1.1 of these Guidelines are prohibited from releasing specimens collected under the federal workplace drug testing program to any individual or entity unless expressly authorized by these Guidelines or in accordance with applicable federal law.

While these Guidelines do not authorize the release of specimens, or portions thereof, to federal employees, the Guidelines afford employees a variety of protections that ensure the identity, security and integrity of their specimens from the time of collection through final disposition of the specimen. There are also procedures that allow federal employees to request the retesting of their specimen (for drugs, adulteration, or substitution) at a different certified laboratory. Furthermore, the Guidelines grant federal employees access to a wide variety of information and records related to the testing of their specimens, including a documentation package that includes, among other items, a copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, and any memoranda generated by the laboratory or Instrumented Initial Test Facility (IITF).

Therefore, the Guidelines offer federal employees and federal agencies transparent and definitive evidence of a specimen's identity, security, control and chain of custody. However, the Guidelines do not entitle employees access to the specimen itself or to a portion thereof. The reason for this prohibition is that specimens collected under the Guidelines are uniquely designed for the purpose of drug and validity testing only. They are not designed for other purposes such as deoxyribonucleic acid (DNA) testing. Furthermore, conducting additional testing outside the parameters of the Guidelines would not guarantee incorporation of the safeguards, quality control protocols, and the exacting scientific standards developed under the Guidelines to ensure the security, reliability and accuracy of the drug testing process.

**Subpart C—Urine Specimen Tests**

Section 3.3(a) includes the same requirement as the current Guidelines for urine specimens collected for federal agency workplace drug testing programs to be tested only for drugs and to determine their validity. While satisfied that the policy as stated in the current Guidelines prohibits other testing (*e.g.,* DNA testing) on a specimen, the Department has removed the phrase ''unless otherwise authorized by law'' and reworded for clarity. The revised section states that specimens must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. The reasons for this prohibition are described above, in comments for Section 2.6.

Section 3.4 lists the drug test analytes and cutoff concentrations for urine. The table in Section 3.4 is the same in the current Guidelines with three notable exceptions. First, the proposed UrMG include the added opiates oxycodone, oxymorphone, hydrocodone, and hydromorphone as initial and confirmatory test analytes. Second, the proposed UrMG include methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test and confirmatory test analytes. The current Guidelines include these two drugs as confirmatory test analytes only. Third, the requirement for initial testing using immunoassay-based technology has been changed to allow initial testing by ''alternate'' technologies (see footnote 2 of the table). This is also the reason for specifying the target analyte for each initial test. Considerable discussion was conducted in DTAB meetings regarding these proposed revisions. The DTAB received input from laboratories, reagent manufacturers, subject matter experts, and the FDA.

For initial tests for opiates and amphetamines using immunoassay, the Department is proposing that the immunoassay be calibrated with one analyte from the group that is identified as the target analyte. Footnote 2 of the table in Section 3.4 includes the proposed criteria for calibrating initial tests for these grouped analytes. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80% or greater. The Department is aware that an FDA-cleared immunoassay meeting these criteria may not exist at the time of the UrMG effective date. If an FDA-cleared immunoassay does not demonstrate at least 80 percent cross-reactivity to each analyte, the laboratory or IITF may use the lowest-reacting analyte to establish a decision point to identify specimens as negative or requiring confirmatory testing. This is accomplished by calibrating the FDA-cleared immunoassay using the manufacturer's target analyte, including a control containing the lowest-reacting analyte at its cutoff concentration in each initial test batch, and comparing the immunoassay responses of specimens in the batch to that of the lowest-reacting analyte control. Alternatively, the laboratory or IITF must use separate immunoassays. The proposed analytes and cutoffs are addressed separately and in detail below. The Department is proposing to permit the use of technologies other than immunoassay techniques for initial drug testing. In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy. The proposed Guidelines allow the use of alternate technologies provided that the laboratory or IITF validates the method in accordance with Section 11 for laboratories or Section 12 for IITFs and demonstrates acceptable performance in the PT program.

The proposed analytes and cutoffs follow.

*Inclusion of Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone*

Misuse and abuse of psychotherapeutic prescription drugs, including opioid pain relievers, are issues of concern for all populations regardless of age, gender, ethnicity, race, or community. Recent data show that opioid-related overdose deaths in the U.S. now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined. In addition to overdose deaths, emergency department visits, substance treatment admissions and economic costs associated with opioid abuse have all increased in recent years. The Department is continuing to work with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug abuse and improve public health.[1]

The Department proposes the inclusion of additional Schedule II prescription medications (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the list of authorized drug tests and cutoff concentrations. This action was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and received by the SAMHSA Administrator in January 2012. The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone is supported by various data. According to the 2012

National Survey on Drug Use and Health, which provides data on illicit drug use in the United Sates, current (past month) nonmedical users aged 12 years and older of prescription psychotherapeutic drugs increased from 2003 (6.5 million) to 2012 (6.8 million).[2] Psychotherapeutic drugs are defined as opioid pain relievers, tranquilizers, sedatives, and stimulants. The abuse of psychotherapeutic drugs non-medically is ranked second behind marijuana, where pain relievers represent the majority of the group. The Drug Abuse Warning Network (DAWN), which provides national estimates of drug-related visits to hospital emergency departments (ED), showed that, of the 1.2 million ED visits involving nonmedical use of pharmaceuticals in 2011, 46.0 percent involved nonmedical use of pain relievers, with 29 percent being narcotic pain relievers.[3] The most frequently involved narcotic pain relievers were oxycodone and hydrocodone. From 2004 to 2011, ED visits involving nonmedical use of narcotic pain relievers increased by 153 percent. ED visits involving opiates/opioids increased by 183 percent during this period, with increases of 438 percent for hydromorphone, 263 percent for oxycodone, and over 100 percent for hydrocodone, as well as fentanyl and morphine. In addition, the National Forensic Laboratory Information System (NFLIS) found that oxycodone and hydrocodone were among the top ten drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories.[4] Among prescription drugs, oxycodone and hydrocodone ranked first and second. Information on over 5 million drug tests in general workplace drug testing shows that the positivity rate for oxycodone and hydrocodone (0.96%) was second only to marijuana in 2012.[5]

The addition of these Schedule II prescription medications will require MRO review to verify legitimate drug use. Consistent with the current Guidelines, the MRO must contact the donor to determine if there is a legitimate medical explanation for a positive result. If the donor provides a legitimate medical explanation (*e.g.,* a valid prescription) for the positive result, the MRO reports the test result as negative to the agency.

The use of medications, specifically Schedule II drugs, without a prescription is a growing concern for the Department in workplace drug testing, and the proposal for their inclusion offers the opportunity to deter nonmedical use of these drugs among federal workers. The Department does note that in recognition of the prescription drug abuse issue, the Department of Defense issued a memorandum on January 30, 2012, announcing the expansion of their drug testing panel to include hydrocodone and benzodiazepines starting on May 1, 2012. Similarly, the Department proposes that federal agencies include the testing of oxycodone, oxymorphone, hydrocodone, and hydromorphone in urine specimens as described below.

*Oxycodone/Oxymorphone*

The Department is proposing to test for oxycodone/oxymorphone using a 100 ng/mL cutoff concentration for the initial test and 50 ng/mL for the confirmatory test cutoff concentration. Both oxycodone and oxymorphone are potent analgesics that are available by prescription for pain relief. Oxycodone is partially metabolized by O-demethylation to oxymorphone and both parent drug and metabolite are excreted in urine following oxycodone administration.[6–10] Following oxymorphone administration, oxymorphone is metabolized and excreted in urine primarily as a glucuronide conjugate of the parent drug.[6 10]

An immunoassay initial test for oxycodone/oxymorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 100 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 50 ng/mL confirmatory test cutoff concentration applies equally to oxycodone and oxymorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 50 ng/mL.

*Hydrocodone/Hydromorphone*

The Department is proposing to test for hydrocodone/hydromorphone using a 300 ng/mL cutoff concentration for the initial test and 100 ng/mL for the confirmatory test cutoff concentration. Both hydrocodone and hydromorphone are potent analgesics that are available by prescription for pain relief. Hydrocodone is partially metabolized by O-demethylation to hydromorphone and both parent drug and metabolite are excreted in urine following hydrocodone administration.[6 9 12–14] Following hydromorphone administration, hydromorphone is metabolized and excreted in urine primarily as a glucuronide conjugate of the parent drug.[15] Hydrocodone has been reported to be a minor metabolite of codeine [16] and hydromorphone has been reported to be a minor metabolite of morphine.[17 18]

An immunoassay initial test for hydrocodone/hydromorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 300 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to hydrocodone and hydromorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 100 ng/mL.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination drug products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, in October 2013, the FDA Center for Drug Evaluation and Research announced the agency's intent to recommend to HHS that hydrocodone combination drug products should be reclassified to Schedule II. FDA stated that this determination came after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which FDA received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

In December 2013, FDA, with the concurrence of the National Institute on Drug Abuse (NIDA), submitted a formal recommendation package to HHS to

reclassify hydrocodone combination drug products into Schedule II. Also in December 2013, the Secretary of HHS submitted the scientific and medical evaluation and scheduling recommendation to the DEA for its consideration. On August 22, 2014, DEA published the Final Rule that moves hydrocodone combination drug products from Schedule III to Schedule II.

*Inclusion of Methylenedioxyamphetamine (MDA) and Methylenedioxyethylamphetamine (MDEA) as Initial Test Analytes*

The Department proposes adding MDA and MDEA as initial test analytes in the list of authorized drug tests and cutoff concentrations. The current Guidelines include these two drugs as confirmatory test analytes only, in conjunction with an initial test for MDMA. Specifying these compounds as initial test analytes (in addition to MDMA) improves their detection by initial tests using immunoassay, and enables detection by initial tests using an alternate technology, as allowed under these proposed Guidelines. All three analytes are Schedule I drugs. The Department is proposing to test for MDMA/MDA/MDEA using a 500 ng/mL cutoff concentration for the initial test and 250 ng/mL for the confirmatory test cutoff concentration.

An immunoassay initial test for MDMA/MDA/MDEA should be calibrated with one of the three analytes and demonstrate sufficient cross-reactivity with the other analytes. The Department proposes that the minimum cross-reactivity with each analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or all analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the three analytes must be equal to or greater than 500 ng/mL. The quantitative sum of the three analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to MDMA, MDA, and MDEA. A positive test would be comprised of one or more analytes with a confirmed concentration equal to or greater than 250 ng/mL.

Section 3.5 authorizes HHS-certified laboratories to perform additional tests to assist the Medical Review Officer (MRO) in making a determination of positive or negative results. The Department believes that additional tests requested by the MRO can provide useful information to determine the veracity of a donor's medical explanation. This is a revision to the current Guidelines, but is consistent with current practices. An example of an additional test currently requested by an MRO is when the laboratory reports a positive methamphetamine result. The MRO may request a d,l-stereoisomer determination for methamphetamine, to determine whether the result could be attributed to use of an over-the-counter nasal inhaler. Another example of current practice is when the laboratory reports a positive THCA result, and the MRO requests testing for cannabivarin, to distinguish marijuana use from dronabinol (*e.g.,* Marinol®).

In Section 3.6, the Department proposes to revise the criteria to report a urine specimen as adulterated based on pH. Specifically, in paragraph 3.6(a), the Department is proposing to raise the low pH cutoff for adulteration from less than 3 to less than 4. This decision is based on the fact that the physiologically minimum achievable urine pH that can be produced by the kidneys is about pH 4.5.[19] Furthermore, there are no known medical conditions or medications that would cause urine pH to be less than 4.5. Any free hydrogen ions present in the renal tubular fluid are either buffered and secreted into urine in the form of ammonium, phosphate, sulfate, and weak organic acid ions with minimal change to the urine pH or they back leak into the extracellular fluid and are not excreted into the urine, which explains the physiological lower limit of 4.5 for urine pH. A proposed pH cutoff for adulteration of less than 4 creates an invalid pH range of ''equal to or greater than 4 and less than 4.5,'' which protects the donor from a pH test result less than 4.5 that could be due to analytical imprecision.

Section 3.8 contains the same criteria as the current Guidelines for reporting a urine specimen as dilute in conjunction with positive or negative drug test results. The section has been revised to clarify the criteria for specific gravity results measured to four-decimal places (*i.e.,* as required when creatinine is less than or equal to 5 mg/dL).

Section 3.9 contains the criteria for reporting an invalid result for a urine specimen. This section contains the same criteria for reporting an invalid result for a urine specimen as in the current Guidelines with four revisions. Paragraph 3.9(b) contains the criteria for reporting a specimen as invalid based on pH. The lower pH range has been changed to ''equal to or greater than 4 and less than 4.5,'' consistent with the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)]. Paragraph 3.9(i) addresses interference using an alternate initial drug test method (*i.e.,* other than immunoassay) as proposed in the UrMG. This section includes an additional criterion in Paragraph 3.9(m) that allows reporting an invalid result when the specimen is not consistent with human urine as evidenced by additional specimen validity test results. This is consistent with the proposed Section 3.5 that allows the MRO to request additional tests. For example, at least one HHS-certified laboratory currently tests their non-regulated workplace urine specimens for a urine biomarker (*i.e.,* uric acid) to distinguish urine of human origin from synthetic urine. The Department believes that such tests can be useful, especially in light of the proliferation of urine substitution products that have been formulated to meet the criteria for routine specimen validity tests (*i.e.,* creatinine and pH). The tests must be forensically acceptable and scientifically sound.

**Subpart D—Collectors**

Sections 4.1 through 4.6 contain the same policies as the current Guidelines in regard to who may or may not collect a specimen, the requirements to be a collector, the requirements to be an observer for a direct observed collection, the requirements to be a trainer for collectors, and what a federal agency must do before a collector is permitted to collect a specimen. The only changes from the current Guidelines are some rewording for clarity and a minor change in the type of mock collections required for collector training in Section 4.3(a)(4).

**Subpart E—Collection Sites**

Sections 5.1 through 5.6 address requirements for collection sites, collection site records, how a collector ensures the security and integrity of a specimen at the collection site, and the privacy requirements when collecting a specimen. Most requirements are the same as in the current Guidelines, but some items have been reworded for clarity. The Department added a new Section 5.3 clarifying that collection site records must be stored at a secure site designated by the collector or the collector's employer. The Department also revised Section 5.4 to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

**Subpart F—Federal Drug Testing Custody and Control Form**

Sections 6.1 and 6.2 are the same as in the current Guidelines, requiring an OMB-approved Federal CCF be used to document custody and control of each specimen at the collection site, and specifying what should occur if the correct OMB-approved CCF is not used.

**Subpart G—Urine Specimen Collection Containers and Bottles**

Sections 7.1 through 7.3 describe requirements for the collection container, temperature strip, and bottles that must be used to for urine specimen collections. The Department has added detailed requirements for these items, to enable proper collection and maintenance of the urine specimen.

Section 7.1 requires a single use container that has a means to measure urine temperature and two specimen bottles for urine collection.

Section 7.2 requires that the urine collection container, including the temperature strip and the bottles, not substantially affect the composition of drug and/or drug metabolites in the specimen. In addition, the two bottles must be sealable and non-leaking and maintain the integrity of the specimen during storage and transport, and must be sufficiently transparent to enable an objective assessment of the A and B specimens' appearance and identification of abnormal physical characteristics upon receipt at the HHS-certified laboratory or IITF.

Section 7.3 details the minimum performance requirements for a collection container and bottles (*i.e.,* required volume capacity and volume markings) and for the thermometer used to measure specimen temperature. The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

**Subpart H—Urine Specimen Collection Procedure**

This subpart addresses the same topics, in the same order, as the OFMG procedures for oral fluid specimen collection. While the procedure is essentially the same as described in the current Guidelines, the Department has reordered and/or reworded steps for clarity and for consistency with the proposed OFMG. Differences exist due to the differences in urine and oral fluid collection procedures. In addition, the Department is proposing to allow federal agencies to authorize collection of oral fluid as an alternate specimen when a donor does not provide an adequate urine specimen. References to agency authorization and collection procedures for oral fluid are applicable only when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 8.5 describes the responsibilities and procedures the collector must follow during and after a urine collection. The Department has revised Section 8.5 to enable a federal agency to authorize collection of oral fluid as an alternate specimen when a donor is unable to provide a sufficient volume of urine within the allowed wait period (*i.e.,* up to three hours). As noted above, this revision will be applicable when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines. Specifically, Paragraph 8.5(f)(2)(iii) instructs the collector to request authorization for the alternate specimen collection when he/she notifies the federal agency representative of the insufficient urine specimen.

Section 8.6 describes the procedures the collector must follow when a donor is unable to provide a urine specimen. The Department has revised Section 8.5 to enable a federal agency to authorize collection of oral fluid as an alternate specimen when a donor is unable to provide a urine specimen. As noted above, this revision will be applicable when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines. Specifically, Paragraph 8.6(b)(2) instructs the collector to request authorization for the alternate specimen collection when he/she notifies the federal agency representative of the donor's inability to provide a urine specimen.

Section 8.7 prohibits collection of an alternate specimen when a donor is unable to provide an adequate urine specimen, unless specifically authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs and by the federal agency. As noted above, Paragraphs 8.5(f)(2)(iii) and 8.6(b)(2) describe the circumstances in which the federal agency representative can authorize the collector to collect an alternate specimen (*e.g.,* oral fluid).

Section 8.14 describes a federal agency's responsibilities for a collection site. The Department has included an additional example of appropriate action that may be taken in response to a reported collection site deficiency: Self-assessment using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs. This document is available on the SAMHSA Web site *http://www.samhsa.gov/workplace*.

**Subpart I—HHS Certification of Laboratories and IITFs**

This subpart contains the same requirements for HHS certification of laboratories and instrumented initial test facilities (IITFs) as the current Guidelines.

Section 9.5 includes the same qualitative and quantitative specifications for PT samples as the current Guidelines. Section 9.19 describes where the monthly list of laboratories and IITFs certified by HHS to conduct forensic drug testing for federal agencies is published. The list will indicate the type of specimen (*e.g.,* urine or oral fluid) that each laboratory is certified to test.

**Subpart J—Blind Samples Submitted by an Agency**

This subpart describes the policies for federal agency blind samples. In Section 10.1, the Department is keeping the annual 3 percent requirement for federal agency blind samples (*i.e.,* as a percentage of the agency's donor specimens) but is proposing to limit the annual number of blind samples to a maximum of 400.

Section 10.2 includes the same requirements for a blind sample as the current Guidelines. The Department has reworded the section for clarity. Also, in Paragraph 10.2(e), the Department added information that blind sample suppliers must provide and specified that the information is to be provided to the collection site/collector sending the sample and, upon request, to the MRO, federal agency, or the Secretary.

In Section 10.4, the Department added that the MRO must contact the laboratory or IITF as the first step after receiving a report for a blind sample with a result that is inconsistent with the expected result.

**Subpart K—Laboratory**

Section 11.10 addresses initial drug test requirements. These are the same as the current Guidelines requirements, except that the Department is proposing to allow the use of technologies other than immunoassay (*i.e.,* alternate initial test technologies). In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the

immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy.

Section 11.11 describes validation requirements for initial drug tests. The Department has included a requirement in Paragraph 11.11(a)(5) for laboratories to assess potential interferences during assay validation. The revision is consistent with current requirements for HHS-certified laboratories. In Paragraphs 11.11(a)(6) and 11.11(c), the Department is proposing additional requirements for alternate technology initial drug tests based on the characteristics of these technologies.

Section 11.13 addresses confirmatory drug test requirements. The Department is proposing to allow analytical procedures using mass spectrometry or other equivalent technologies. Based on ongoing reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied newer instruments and technologies, the Department believes that scientifically valid confirmatory methods other than combined chromatographic and mass spectrometric methods can be used to successfully detect and report the drug analytes in Subpart C—Urine Specimen Drug Tests.

Section 11.14 describes validation requirements for confirmatory tests. The Department has included a requirement for laboratories to assess matrix effects when validating a confirmatory drug test using liquid chromatography coupled with mass spectrometry and has added the requirement for laboratories to verify each new lot of reagent prior to placement into service. These revisions are consistent with current requirements for HHS-certified laboratories.

In Section 11.17, the Department added the requirement for laboratories to verify each new lot of reagent for specimen validity testing prior to placement into service, consistent with current requirements for HHS-certified laboratories.

The requirements for conducting each specimen validity test are the same as the current Guidelines, with the exception of pH testing and quality control requirements in Section 11.18(c) which have been revised in accordance with the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)].

Section 11.19 addresses laboratory requirements for reporting test results. The Department made a change to wording in Section 11.19(a), deleting the requirement for laboratories to report results directly to the MRO, to allow the use of external service providers. Providing test results electronically to MROs can be timely and cost-effective, and is expected to increase following implementation of the Federal Custody and Control Form (CCF) as an electronic document. Section 11.19(n) was revised to require HHS-certified laboratories and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes test results and donor personal identifying information (PII), and to limit access to any data transmission, storage, and retrieval system. Changes have been made to the criteria for reporting a specimen as adulterated or as invalid based on low pH [*i.e.,* Sections 11.19(d) and 11.19(h)(2)] to reflect the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)]. In Section 11.19(p), the Department has added the requirement for the laboratory to send a legible image or copy of the Federal CCF for rejected specimens to the MRO, as is current practice.

The Department revised Section 11.21(a) to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

Section 11.22 describes the semiannual statistical summary report that a laboratory must provide to a federal agency for urine testing. The Department is proposing to require the laboratory to submit a copy (paper or electronic) of each statistical summary report to the Secretary or designated HHS representative.

Section 11.23 is a new section addressing the laboratory information to be made available to a federal agency and describes the contents of a standard laboratory documentation package, which are the same as in the current Guidelines. The Department is proposing that a federal agency may obtain laboratory information related to a positive, adulterated, or substituted drug test reported for a federal employee tested in its workplace program, as well as any relevant certification, review, or revocation of certification records for the laboratory.

Section 11.24 was modified to clarify that specimens are not a part of the information package that donors can receive from HHS-certified laboratories.

**Subpart L—Instrumented Initial Test Facility (IITF)**

This subpart addresses requirements for IITFs. Most requirements remain the same as the current Guidelines. The proposed revisions, detailed below, are consistent with the proposed revisions for laboratories in Section 11.

Section 12.9 addresses initial drug test requirements for IITFs. The Department is proposing to allow IITFs to use technologies other than immunoassay (*i.e.,* alternate initial test technologies). In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy.

Section 12.10 describes validation requirements for initial drug tests. The Department has included a requirement in Paragraph 12.10(a)(5) for IITFs to assess potential interferences during assay validation. The revision is consistent with current requirements for HHS-certified IITFs. In Paragraphs 12.10(a)(6) and 12.10(c), the Department is proposing additional requirements for alternate technology initial drug tests based on the characteristics of these technologies.

In Section 12.13, the Department added the requirement for IITFs to verify each new lot of reagent for specimen validity testing prior to placement into service, consistent with current requirements for HHS-certified IITFs.

Section 12.15 addresses IITF requirements for reporting test results. The Department made a change to wording in Section 12.15(a), deleting the requirement for IITFs to report results directly to the MRO, to allow the use of external service providers. Providing test results electronically to MROs can be timely and cost-effective, and is expected to increase following implementation of the Federal Custody and Control Form (CCF) as an electronic document. Section 12.15(e) was revised to require HHS-certified IITFs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes test results and donor PII, and to limit access to any data transmission, storage, and retrieval system. In Section 12.15(g), the Department has added the requirement for the IITF to send a legible image or copy of the Federal CCF for rejected specimens to the MRO.

The Department revised Section 12.18(a) to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and

is consistent with the Paperwork Reduction Act.

Section 12.19 describes the semiannual statistical summary report that an IITF must provide to a federal agency for urine testing. The Department is proposing to require the IITF to submit a copy of each semiannual statistical summary report (paper or electronic) to the Secretary or designated HHS representative.

Section 12.20 is a new section addressing the IITF information to be made available to a federal agency and describes the contents of a standard IITF documentation package, which are the same as in the current Guidelines. The Department is proposing that a federal agency may obtain IITF information related to a positive, adulterated, or substituted drug test reported by a laboratory for a federal employee tested in its workplace program, as well as any relevant certification, review, or revocation of certification records for the IITF.

**Subpart M—Medical Review Officer (MRO)**

Section 13.1 describes who may serve as an MRO. With the inclusion of additional Schedule II prescription medications in the Guidelines and the ever-changing field of drug testing, medical review of drug test results is more complex today than before. Therefore, the Department proposes to incorporate MRO requalification training and reexamination on a regular basis (at least every five years). The UrMG and OFMG do not include a requirement for MROs to obtain continuing education units (CEUs). The Department understands that it would be difficult to determine whether CEUs obtained are related to federal agency drug testing. The requalification requirement every five years will assure agency auditors and inspectors and regulated employers that MROs are appropriately qualified. This requirement is not expected to increase costs to MROs. Current practices for MRO requirements have equivalent standards but vary among MRO training entities. These requirements will standardize the length of time each MRO is required to take a requalification examination. Currently, some MRO requalification periods are longer than five years, while others are less than five years. The Department assumes that the costs to those MROs that have requalification periods over five years will be offset by the cost savings to MROs that have periods shorter than five years. Thus, the Department has not estimated any costs associated with this provision, but it welcomes comment on this assumption.

The Department anticipates that MROs will continue to obtain CEUs by virtue of maintaining their medical licensure requirements. In addition, the MRO certification/training entities provide MRO manuals and periodic newsletters with updates on federal drug testing program requirements. However, the Department is seeking comments on requiring MRO requalification CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification.

MROs play a key role in the federal safety program and maintain the balance between the safety and privacy objectives of the program. The MRO's role in gathering and evaluating the medical evidence and providing due process is imperative. These are duties that must be carried out by the MRO, and cannot be delegated to other personnel who are not certified by an MRO entity.

The MRO is charged with certain important medical and administrative duties. The MRO must have detailed knowledge of the effects of medications and other potential alternative medical explanations for laboratory reported drug test results. He or she is responsible for determining whether legitimate medical explanations are available to explain an employee's drug test result. This medical review process has become far more complex as a result of specimen validity testing and the myriad of donor explanations for adulterated, substituted, and invalid laboratory test results.

In addition, MROs confer with prescribing physicians in making decisions about prescription changes so that alternative medications can be used that will not impact public safety. Similarly, the MRO is required to report to employers the employees' prescription and over-the-counter medication use (or dangerous combinations of use) that the MRO believes will negatively affect duty performance. In addition, the MRO is required to medically assess referral physician examinations and evaluations in certain positive and refusal-to-test situations. These, too, have become more complex over time.

Section 13.2 describes how nationally recognized entities or subspecialty boards that certify MROs are approved. The Department is proposing to extend the due date for resubmission of qualifications for HHS approval from each year to every two years and to publish the list of approved entities at least every two years, rather than annually. The revised time periods appear sufficient to ensure that educational material is updated at least every two years and the Department requiring the nationally recognized entities that approves MROs ensures the qualifications are being met. The Department has also revised this section to require submission of the certification examination delivery method along with other documentation for review.

Section 13.3 describes the training that is required before a physician may serve as an MRO. With the issue of prescription drug abuse and the inclusion of additional opiates to the federal drug-testing panel, MROs have the difficult task of interpreting positive drug test results from prescription drugs. Further guidance on these drug test results will be included in the MRO manual. The Department has added a requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. MROs performing the review of federal employee drug test results should be aware of prevention and treatment opportunities for individuals and can provide information to the donor.

The Department also revised Section 13.4 to allow the MRO to discard hardcopy records 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

Section 13.5 describes MRO actions when reviewing a urine specimen's test results. Section 13.5(d) contains the same procedure as the current Guidelines: When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result. If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. The Department added a new Section 13.5(c) to address multiple test results for one specimen and added Section 13.5(h) to address MRO procedures for multiple specimens from the same testing event (*e.g.,* when the collector forwarded to the laboratory a urine specimen with temperature out of range and the subsequently collected specimen—urine or another authorized specimen type). In Paragraphs 13.5(b) and 13.5(g), the Department added instructions for handling recollected negative/dilute or invalid specimens that provide the same results as the first specimen (*i.e.,* when another specimen

was collected from a donor because of a negative/dilute or invalid result, and the recollected specimen provides the same result as the first specimen). The proposed revisions provide a final resolution to report such drug tests, which were not adequately addressed in the current Guidelines. The Department revised Section 13.5(i) to specify the type of specimen (*i.e.,* urine) to be collected from the donor following a cancelled test for a rejected specimen.

Section 13.6 describes what an MRO must do when the collector reports that a donor did not provide a sufficient amount of urine for a drug test. For those instances in which the donor did not provide an adequate urine specimen and the federal agency authorized collection of another specimen type (*e.g.,* oral fluid), the Department is proposing that the MRO review and report those results. If the federal agency did not authorize collection of another specimen type, the current Guidelines procedures remain in effect (*i.e.,* medical evaluation). The Department revised this section to address collection of an alternative specimen for any subsequent tests when the donor has a permanent or long-term medical condition that prevents provision of a sufficient volume of urine for the drug test. As noted previously, a federal agency may authorize collection of oral fluid only when the OFMG are effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 13.7 describes what an MRO must do when a donor has a permanent or long-term medical condition that prevents him or her from providing a sufficient amount of urine, a negative test is required (*i.e.,* for a federal agency applicant/pre-employment, follow-up, or return-to-duty test), and the federal agency did not authorize collection of another specimen type (*e.g.,* oral fluid). As noted previously, a federal agency may authorize collection of oral fluid only when the OFMG are effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 13.9 describes how an MRO reports a primary (A) specimen result to an agency. The Department revised Section 13.9(a) to address MRO use of external service providers. The revised section requires MROs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes donor PII, and to limit access to any data transmission, storage, and retrieval system. The Department is also proposing to delete the requirement in Paragraph 13.9(c) for the MRO to send a paper copy of the Federal CCF or separate letter/memorandum. The MRO may report results electronically.

**Subpart N—Split Specimen Tests**

The Department is proposing to revise Section 14.1(c) to clarify that, in a case where a B specimen is not available for testing, the MRO reports only to the federal agency and not to the donor. This is consistent with the requirement in the next sentence that no notice be given to the donor until immediately before the observed recollection.

Section 14.3(a) addresses criteria for reconfirming an adulterated result. The low pH cutoff in Section 14.3(a)(1) has been changed to reflect the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)].

Section 14.5 describes who receives the split specimen report from the laboratory. The Department reworded this section to address MRO use of external service providers, similar to the change made to Section 11.19(a) for primary specimen reports.

Section 14.7 describes how an MRO reports a split (B) specimen result to an agency. The Department revised Section 14.7(a) to address MRO use of external service providers. The revised section requires MROs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes donor PII, and to limit access to any data transmission, storage, and retrieval system. The Department revised Section 14.7(c) to clarify that MRO must use the Federal CCF or separate letter/memorandum to report all split specimens (*i.e.,* not just positive, adulterated, or substituted specimens), and deleted the requirement for the MRO to send paper copies of these documents. The MRO may report results electronically.

**Subpart O—Criteria for Rejecting a Specimen for Testing**

In Section 15.1, the Department is proposing a new Paragraph 15.1(e) requiring specimen rejection if the accessioner has not documented the primary (A) seal condition at the time of accessioning and the split (B) specimen cannot be redesignated as the primary (A) specimen. This is consistent with current practice. The Department maintains that relying on the accessioner's recall of a particular specimen's bottle seal condition is not a forensically acceptable practice.

**Subpart P—Laboratory or IITF Suspension/Revocation Procedures**

This subpart includes procedures to revoke or suspend the HHS-certification of laboratories and IITFs. These are the same as in the current Guidelines.

**Impact of These Guidelines on Government Regulated Industries**

The Department is aware that these proposed new Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final UrMG revisions into their programs under their own authority.

**Topics of Special Interest**

The Department requests public comment on all aspects of this notice. However, the Department is providing the following list of areas for which specific comments are requested.

Section 3.4 lists the proposed new analytes oxycodone, oxymorphone, hydrocodone, and hydromorphone and their cutoff concentrations. The Department is specifically requesting comments on these revisions.

Section 13.1 describes proposed requirements for MRO requalification training and reexamination on a regular basis (*i.e.,* every five years) but does not require MROs to obtain continuing education units (CEUs). The Department is seeking comments on requiring MRO CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required.

**Regulatory Impact and Notices**

The Department welcomes public comment on all figures and assumptions used for the regulatory impact assessment described in this section.

*Executive Orders 13563 and 12866*

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) states ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' This notice proposes a

regulatory approach that will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the proposed Guidelines under Executive Order 12866, which directs federal 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).

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The proposed Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs. However, the statute under which the mandatory guidelines were created (Pub. L. 100–71, section 503(a)(3)) required notice and comment apart from the APA. This provision provides the following: Notwithstanding any provision of chapter 5 of title 5, United States Code, the mandatory guidelines to be published pursuant to subsection (a)(l)(A)(ii) shall be published and made effective exclusively according to the provisions of this paragraph. Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services shall be published in the **Federal Register**, and interested persons shall be given not less than 60 days to submit written comments on the proposed mandatory guidelines. Following review and consideration of written comments, final mandatory guidelines shall be published in the **Federal Register** and shall become effective upon publication.

*Need for Revisions to the Guidelines*

The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in the URMG was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and approved by the SAMHSA Administrator in January 2012. This action is supported by various data, described in this preamble.[1–4] In addition, in 2008, 12 percent of military personnel admitted to the illicit use of prescription medications. Prevalence testing by the Department of Defense (DoD) in 2009 indicated that prescription drug abuse exceeded illegal drug abuse. Because of this, hydrocodone and hydromorphone testing was added to the regular DoD drug testing panel in 2011.

*Costs*

Costs associated with the implementation of testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal because the Department has determined that all HHS certified laboratories testing specimens from federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA and MDEA since the current immunoassays can be adapted to test for these analytes. Laboratory personnel are currently trained and test methods have been implemented. However, there will be some administrative costs associated with adding these analytes. Prior to being allowed to test regulated specimens for these compounds, HHS certified laboratories will be required to demonstrate that their performance meets Guideline requirements by testing three (3) groups of PT samples. The Department will provide the PT samples through the National Laboratory Certification Program (NLCP) at no cost to the certified laboratories. Based on costs charged for specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each certified laboratory.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

For the added opiate analytes, the two immunoassays currently used for oxycodone and oxymorphone meet the requirements, and two of the three existing opiate immunoassays used in certified laboratories meet the requirements for hydrocodone and hydromorphone analysis. The opiate immunoassay that does not have sufficient cross-reactivity would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, hydromorphone, is used to establish a decision point. Therefore, the Department assumes that all certified laboratories will elect to use existing immunoassays. Thus, the costs associated with implementing the initial tests for these analytes are expected to be *de minimis.*

For amphetamines, one of the three existing methylenedioxymethamphetamine (MDMA) immunoassays used in certified laboratories meets the requirements. The remaining two exhibit insufficient cross-reactivity for MDA. These two immunoassays would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, MDA, is used to establish a decision point. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance. Again, the Department assumes that certified laboratories will use the existing immunoassays and incur *de minimis* costs.

Once the testing has been implemented, the cost per specimen for initial testing for the added analytes will range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported positive, due to sample preparation and analysis costs. Based on information from non-regulated workplace drug testing for these analytes and testing performed by the Department on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen. This

would indicate that the cost per specimen submitted for testing will increase by $0.11–$0.30.

The addition of the Schedule II prescription medications will require MRO review to verify legitimate drug use. Based on the positivity rates from non-regulated workplace drug testing for these analytes and the additional review of specimens confirmed positive for prescription medications, MRO costs are estimated to increase by approximately 3%. This 3% cost increase is expected to occur gradually as agencies' existing contracts expire and they renegotiate the terms of new contracts, with an increase to the total cost of a federal drug test over time to between $0.60–$1.35. This cost would indicate a total cost for federal agencies of $83,700 to $188,325 in the urine testing program.

The additional costs for testing and MRO review will be incorporated into the overall cost for the federal agency submitting the specimen to the laboratory. The estimation of costs incurred is based upon overall cost to the federal agency because the review of positive specimens is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Agencies may also incur some costs for training of federal employees such as drug program coordinators due to implementation of the revised Guidelines. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $54,000 and $69,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage).

RECURRING ANNUAL COSTS SUMMARY TABLE

| | Lower bound | Upper bound |
|---|---|---|
| Reagent Costs | $368,730.00 | $1,229,100.00 |
| Additional Confirmatory tests | 307,275.00 | 614,550.00 |
| MRO Costs | 3,687,300.00 | 8,296,425.00 |
| Total annual costs | 4,363,305.00 | 10,140,075.00 |

UPFRONT (ONE-TIME) COSTS SUMMARY TABLE

| | Lower bound | Upper bound |
|---|---|---|
| Performance Testing | $27,900.00 | $55,800.00 |
| Training | 54,000 | 69,000 |
| Total | 81,900.00 | 124,800.00 |

*Benefits*

The potential benefits of deterring use of oxycodone, oxymorphone, hydrocodone and hydromorphone are the prevention of their side effects (*e.g.,* anxiety, dizziness, drowsiness, fatigue, and other neurological effects), which will result in a healthier and more alert workforce as well as avoid the issues associated with addiction and rehabilitation. Since the personnel tested under this program are in positions that are safety sensitive, potential benefits include decreased risk of transportation accidents, decreased risk of low-probability high consequence events, more responsible workforce in positions of public trust, and potentially reducing individuals' dependence or addiction and the personal benefits associated with those conditions.

Considering the potential health and performance costs of narcotic abuse, the benefits to the federal workplace and the individuals within that workplace justify the inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in Federal Workplace Drug Testing programs.

*Regulatory Flexibility Analysis*

For the reasons outlined above, the Secretary has determined that the proposed Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the UrMG will not require addition expenditures. Therefore, an initial regulatory flexibility analysis is not required for this notice.

The Secretary has determined that the proposed Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

*Unfunded Mandates*

The Secretary has examined the impact of the proposed Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the proposed Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

*Environmental Impact*

The Secretary has considered the environmental effects of the UrMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

*Executive Order 13132: Federalism*

The Secretary has analyzed the proposed Guidelines in accordance with Executive Order 13132: Federalism.

Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary is proposing to revise the standards for certification of laboratories engaged in urine fluid drug testing for federal agencies and the use of urine testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

*Paperwork Reduction Act of 1995*

The proposed Guidelines contain information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 [the PRA 44 U.S.C. 3507(d)]. Information collection and recordkeeping requirements which would be imposed on laboratories engaged in drug testing for federal agencies concern quality assurance and quality control documentation, reports, performance testing, and inspections as set out in subparts H, I, K, L, M and N. To facilitate ease of use and uniform reporting, a Federal CCF for each type of specimen collected will be developed as referenced in section 6.1. The Department has submitted the information collection and recordkeeping requirements contained in the proposed Guidelines to OMB for review and approval.

*Privacy Act*

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

*Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The proposed Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

**Information Collection/Record Keeping Requirements**

The information collection requirements (*i.e.*, reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect until final Guidelines including the use of another specimen matrix are issued.

The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* The Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens.

*Description:* The Mandatory Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

*Description of Respondents:* Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

*The burden estimates in the tables below are based on the following number of respondents:* 38,000 donors who apply for employment in testing designated positions, 100 collectors, 30 urine specimen testing laboratories, 5 IITFs, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 9.2(a)(1) | Laboratory or IITF required to submit application for certification. | 10 | 1 | 3 | 30 |
| 9.12(a)(3) | Materials to submit to become an HHS inspector. | 10 | 1 | 2 | 20 |
| 11.3(a) | Laboratory submits qualifications of RP to HHS. | 10 | 1 | 2 | 20 |
| 11.4(c) | Laboratory submits information to HHS on new RP or alternate RP. | 10 | 1 | 2 | 20 |
| 11.22 | Specifications for laboratory semi-annual statistical report of test results to each federal agency. | 10 | 5 | 0.5 | 25 |
| 12.3(a) | IITF submits qualifications of RT to HHS. | ..... | ..... | ..... | ..... |
| 12.4(c) | IITF submits information to HHS on new RT or alternate RT. | ..... | ..... | ..... | ..... |
| 12.19 | Specifications for IITF semi-annual statistical report of test results to each federal agency. | ..... | ..... | ..... | ..... |
| 13.9 and 14.7 | Specifies that MRO must report all verified primary and split specimen test results to the federal agency. | 100 | 5 | *0.05 | 25 |
| 16.1(b) & 16.5(a) | Specifies content of request for informal review of suspension/ proposed revocation of certification. | 1 | 1 | 3 | 3 |
| 16.4 | Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed. | 1 | 1 | 0.5 | 0.5 |
| 16.6 | Requires appellant to notify reviewing official of resolution status at end of abeyance period. | 1 | 1 | 0.5 | 0.5 |
| 16.7(a) | Specifies contents of appellant submission for review. | 1 | 1 | 50 | 50 |
| 16.9(a) | Specifies content of appellant request for expedited review of suspension or proposed revocation. | 1 | 1 | 3 | 3 |
| 16.9(c) | Specifies contents of review file and briefs. | 1 | 1 | 50 | 50 |
| Total | ..... | 156 | ..... | ..... | 247 |

*3 min.

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF [Sections 1.8, 8.9]; collector annotates the Federal CCF when a sample is a blind sample [Section 10.3(a)]; MRO notifies the federal agency and HHS when an error occurs on a blind sample [Section 10.4(c)]; and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide a urine specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 8.3(a), 8.5(f)(2)(iii), 8.6(b)(2) | Collector must contact federal agency point of contact. | 100 | 1 | *0.05 | 5 |
| 11.23, 11.24 | Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO. | 10 | 10 | 3 | 1,500 |

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 12.20, 12.21 | Information on drug test that IITF must provide to federal agency upon request or to donor through MRO. | | | | |
| 13.8(b) | MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported. | 100 | 5 | 3 | 1,500 |
| Total | | 210 | | | 3,505 |

* 3 min.

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: The collector must explain the basic collection procedure to the donor and answer any questions [Section 8.3(e) and (g)]. SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

| Section | Purpose | Number of respondents | Responses/ respondent | Hours/ response | Total hours |
|---|---|---|---|---|---|
| 8.3, 8.5, 8.8 | Collector completes Federal CCF for specimen collected. | 100 | 380 | * 0.07 | 2,534 |
| 8.8(d) & (f) | Donor initials specimen labels/ seals and signs statement on the Federal CCF. | 38,000 | 1 | ** 0.08 | 3,167 |
| 11.8(a) & 11.19 | Laboratory completes Federal CCF upon receipt of specimen and before reporting result. | 10 | 3,800 | *** 0.05 | 1,900 |
| 12.8(a) & 12.15 | IITF completes Federal CCF upon receipt of specimen and before reporting result. | | | | |
| 13.4(d)(4), 13.9(c), 14.7(c) | MRO completes Federal CCF before reporting the primary or split specimen result. | 100 | 380 | *** 0.05 | 1,900 |
| 14.1(b) | MRO documents donor's request to have split specimen tested. | 300 | 1 | *** 0.05 | 15 |
| Total | | 38,510 | | | 9,516 |

* 4 min.
** 5 min.
*** 3 min.

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [Section 4.3(a)(3)] and the documentation must be maintained in the collector's training file [Section 4.3(c)]. SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a federal agency specimen, the collector is required to provide a statement [Section 6.2(b)] explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H [Sections 8.4(c), 8.5(d)(2), 8.5(e)(1) and (2)] requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries are included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records [*i.e.*, Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.11(a); 11.14(a); 11.17; 11.21(a), (b), and (c); 11.22; 11.23(a) and 11.24. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 13,268 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved

by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS'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.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202–395–6974 (fax).

## References


1. U.S. Department of Health and Human Services, Behavioral Health Coordinating Committee, Prescription Drug Abuse Subcommittee, *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities.* Department of Health and Human Services, 2013. *http://www.cdc.gov/HomeandRecreationalSafety/pdf/HHS_Prescription_Drug_Abuse_Report_09.2013.pdf* (accessed 15 September 2014).
2. Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings,* NSDUH Series H–46, HHS Publication No. (SMA) 13–4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
3. Substance Abuse and Mental Health Services Administration, *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits.* HHS Publication No. (SMA) 13–4760, DAWN Series D–39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
4. U.S. Drug Enforcement Administration, Office of Diversion Control, 2013. *National Forensic Laboratory Information System: Year 2012 Annual Report.* Springfield, VA: U.S. Drug Enforcement Administration.
5. Quest Diagnostics Incorporated, *Drug Use Among American Workers Declined 74% Over the Past 25 Years, Finds Unprecedented Analysis of More Than 125 Million Workplace Urine Tests*, *http://blog.employersolutions.com/wp-content/uploads/2013/11/dti25-press-release-11-18-2013.pdf*, 18 November 2013 (accessed 19 August 2014).
6. Smith, M.L., Hughes, R.O., Levine, B., Dickerson, S., Darwin, W.D., and Cone, E.J. (1995), Forensic drug testing for opiates. VI. Urine testing for hydromorphone, hydrocodone, oxymorphone, and oxycodone with commercial opiate immunoassays and gas chromatography-mass spectrometry. J. Anal. Toxicol., 19, 18–26.
7. Cone, E.J., Zichterman, A., Heltsley, R., Black, D.L., Cawthon, B., Robert, T., Moser, F., and Caplan, Y.H. (2010), Urine testing for norcodeine, norhydrocodone, and noroxycodone facilitates interpretation and reduces false negatives. Forensic Sci. Int., 198, 58–61.
8. Lalovic, B., Kharasch, E., Hoffer, C., Risler, L., Liu-Chen, L.Y., and Shen, D.D. (2006), Pharmacokinetics and pharmacodynamics of oral oxycodone in healthy human subjects: role of circulating active metabolites. Clin. Pharmacol. Ther., 79, 461–479.
9. Heltsley, R., Zichterman, A., Black, D.L., Cawthon, B., Robert, T., Moser, F., Caplan, Y.H., and Cone, E.J. (2010), Urine drug testing of chronic pain patients. II. Prevalence patterns of prescription opiates and metabolites. J. Anal. Toxicol., 34, 32–38.
10. Poyhia, R., Seppala, T., Olkkola, K.T., and Kalso, E. (1992), The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. Br. J. Clin. Pharmacol., 33, 617–621.
11. Yee, D.A., Best, B.M., Atayee, R.S., and Pesce, A.J. (2012), Observations on the urine metabolic ratio of oxymorphone to oxycodone in pain patients. J. Anal. Toxicol., 36, 232–238.
12. Cone, E.J., Darwin, W.D., Gorodetzky, C.W., and Tan, T. (1978), Comparative metabolism of hydrocodone in man, rat, guinea pig, rabbit, and dog. Drug Metab. Dispos., 6, 488–493.
13. Cone, E.J. and Darwin, W.D. (1978), Simultaneous determination of hydromorphone, hydrocodone and their 6a-and 6B hydroxy metabolites in urine using selected ion recording with methane chemical ionization. Biochem. Mass Spectrom., 5, 291–295.
14. Valtier, S. and Bebarta, V.S. (2012), Excretion profile of hydrocodone, hydromorphone and norhydrocodone in urine following single dose administration of hydrocodone to healthy volunteers. J. Anal. Toxicol., 36, 507–514.
15. Cone, E.J., Phelps, B.A., and Gorodetzky, C.W. (1977), Urinary excretion of hydromorphone and metabolites in humans, rats, dogs, guinea pigs, and rabbits. J.Pharm.Sci., 66, 1709–1713.
16. Oyler, J.M., Cone, E.J., Joseph, R.E., Jr., and Huestis, M.A. (2000), Identification of hydrocodone in human urine following controlled codeine administration. J. Anal. Toxicol., 24, 530–535.
17. Cone, E.J., Heit, H.A., Caplan, Y.H., and Gourlay, D. (2006), Evidence of morphine metabolism to hydromorphone in pain patients chronically treated with morphine. J. Anal. Toxicol., 30, 1–5.
18. Cone, E.J., Caplan, Y.H., Moser, F., Robert, T., and Black, D. (2008), Evidence that morphine is metabolized to hydromorphone but not to oxymorphone. J. Anal. Toxicol., 32, 319–323.
19. Cook, J.D., Strauss, K.A., Caplan, Y.H., LoDico, C.P., Bush, D.M. (2007), Urine pH: the effects of time and temperature after collection. J. Anal. Toxicol., 31, 486–496.


Dated: May 4, 2015.

**Pamela S. Hyde,**

*Administrator, SAMHSA.*

Dated: May 7, 2015.

**Sylvia M. Burwell,**

*Secretary.*

For reasons set forth in the preamble, the Department proposes to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include Mandatory Guidelines using Urine Specimens to read as follows:

## MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING URINE SPECIMENS

### Subpart A—Applicability

1.1 To whom do these Guidelines apply?
1.2 Who is responsible for developing and implementing these Guidelines?
1.3 How does a federal agency request a change from these Guidelines?
1.4 How are these Guidelines revised?
1.5 What do the terms used in these Guidelines mean?
1.6 What is an agency required to do to protect employee records?
1.7 What is a refusal to take a federally regulated drug test?
1.8 What are the potential consequences for refusing to take a federally regulated drug test?

### Subpart B—Urine Specimens

2.2 Under what circumstances may a urine

specimen be collected?
2.3 How is each urine specimen collected?
2.4 What volume of urine is collected?
2.5 How does the collector split the urine specimen?
2.6 When may an entity or individual release a urine specimen?

**Subpart C—Urine Specimen Tests**

3.1 Which tests are conducted on a urine specimen?
3.2 May a specimen be tested for additional drugs?
3.3 May any of the specimens be used for other purposes?
3.4 What are the drug test cutoff concentrations for urine?
3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?
3.6 What criteria are used to report a urine specimen as adulterated?
3.7 What criteria are used to report a urine specimen as substituted?
3.8 What criteria are used to report a urine specimen as dilute?
3.9 What criteria are used to report an invalid result for a urine specimen?

**Subpart D—Collectors**

4.1 Who may collect a specimen?
4.2 Who may not collect a specimen?
4.3 What are the requirements to be a collector?
4.4 What are the requirements to be an observer for a direct observed collection?
4.5 What are the requirements to be a trainer for collectors?
4.6 What must a federal agency do before a collector is permitted to collect a specimen?

**Subpart E—Collection Sites**

5.1 Where can a collection for a drug test take place?
5.2 What are the requirements for a collection site?
5.3 Where must collection site records be stored?
5.4 How long must collection site records be stored?
5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
5.6 What are the privacy requirements when collecting a urine specimen?

**Subpart F—Federal Drug Testing Custody and Control Form**

6.1 What federal form is used to document custody and control?
6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

**Subpart G—Urine Specimen Collection Containers and Bottles**

7.1 What is used to collect a urine specimen?
7.2 What are the requirements for a urine collection container and specimen bottles?
7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

**Subpart H—Urine Specimen Collection Procedure**

8.1 What privacy must the donor be given when providing a urine specimen?
8.2 What must the collector ensure at the collection site before starting a urine specimen collection?
8.3 What are the preliminary steps in the urine specimen collection procedure?
8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?
8.5 What steps does the collector take during and after the urine specimen collection procedure?
8.6 What procedure is used when the donor states that he or she is unable to provide a urine specimen?
8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?
8.8 How does the collector prepare the urine specimens?
8.9 When is a direct observed collection conducted?
8.10 How is a direct observed collection conducted?
8.11 When is a monitored collection conducted?
8.12 How is a monitored collection conducted?
8.13 How does the collector report a donor's refusal to test?
8.14 What are a federal agency's responsibilities for a collection site?

**Subpart I—HHS Certification of Laboratories and IITFs**

9.1 Who has the authority to certify laboratories and IITFs to test urine specimens for federal agencies?
9.2 What is the process for a laboratory or IITF to become HHS-certified?
9.3 What is the process for a laboratory or IITF to maintain HHS certification?
9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?
9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?
9.6 What are the PT requirements for an applicant laboratory?
9.7 What are the PT requirements for an HHS-certified urine laboratory?
9.8 What are the PT requirements for an applicant IITF?
9.9 What are the PT requirements for an HHS-certified IITF?
9.10 What are the inspection requirements for an applicant laboratory or IITF?
9.11 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?
9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?
9.13 What happens if an applicant laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?
9.14 What happens if an HHS-certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?
9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?
9.16 What factors are considered in determining whether to suspend a laboratory's or an IITF's HHS certification?
9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?
9.18 May a laboratory or IITF that had its HHS certification revoked be recertified to test federal agency specimens?
9.19 Where is the list of HHS-certified laboratories and IITFs published?

**Subpart J—Blind Samples Submitted by an Agency**

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories or IITFs?
10.2 What are the requirements for blind samples?
10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?
10.4 What happens if an inconsistent result is reported for a blind sample?

**Subpart K—Laboratory**

11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?
11.2 What are the responsibilities of the responsible person (RP)?
11.3 What scientific qualifications must the RP have?
11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?
11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?
11.7 What security measures must an HHS-certified laboratory maintain?
11.8 What are the laboratory chain of custody requirements for specimens and aliquots?
11.9 What test(s) does an HHS-certified laboratory conduct on a urine specimen received from an IITF?
11.10 What are the requirements for an initial drug test?
11.11 What must an HHS-certified laboratory do to validate an initial drug test?
11.12 What are the batch quality control requirements when conducting an initial drug test?
11.13 What are the requirements for a confirmatory drug test?
11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?
11.15 What are the batch quality control requirements when conducting a confirmatory drug test?
11.16 What are the analytical and quality control requirements for conducting specimen validity tests?
11.17 What must an HHS-certified laboratory do to validate a specimen validity test?
11.18 What are the requirements for

conducting each specimen validity test?
11.19 What are the requirements for an HHS-certified laboratory to report a test result?
11.20 How long must an HHS-certified laboratory retain specimens?
11.21 How long must an HHS-certified laboratory retain records?
11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?
11.23 What HHS-certified laboratory information is available to a federal agency?
11.24 What HHS-certified laboratory information is available to a federal employee?
11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?
11.26 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?

**Subpart L—Instrumented Initial Test Facility (IITF)**

12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?
12.2 What are the responsibilities of the responsible technician (RT)?
12.3 What qualifications must the RT have?
12.4 What happens when the RT is absent or leaves an HHS-certified IITF?
12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?
12.6 What qualifications and training must other personnel of an HHS-certified IITF have?
12.7 What security measures must an HHS-certified IITF maintain?
12.8 What are the IITF chain of custody requirements for specimens and aliquots?
12.9 What are the requirements for an initial drug test?
12.10 What must an HHS-certified IITF do to validate an initial drug test?
12.11 What are the batch quality control requirements when conducting an initial drug test?
12.12 What are the analytical and quality control requirements for conducting specimen validity tests?
12.13 What must an HHS-certified IITF do to validate a specimen validity test?
12.14 What are the requirements for conducting each specimen validity test?
12.15 What are the requirements for an HHS-certified IITF to report a test result?
12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?
12.17 How long must an HHS-certified IITF retain a specimen?
12.18 How long must an HHS-certified IITF retain records?
12.19 What statistical summary report must an HHS-certified IITF provide?
12.20 What HHS-certified IITF information is available to a federal employee?
12.21 What types of relationships are prohibited between an HHS-certified IITF and an MRO?
12.22 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

**Subpart M—Medical Review Officer (MRO)**

13.1 Who may serve as an MRO?
13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?
13.3 What training is required before a physician may serve as an MRO?
13.4 What are the responsibilities of an MRO?
13.5 What must an MRO do when reviewing a urine specimen's test results?
13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?
13.7 What happens when an individual is unable to provide a sufficient amount of urine for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?
13.8 Who may request a test of a split (B) specimen?
13.9 How does an MRO report a primary (A) specimen test result to an agency?
13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?

**Subpart N—Split Specimen Tests**

14.1 When may a split (B) specimen be tested?
14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?
14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?
14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?
14.5 Who receives the split (B) specimen result?
14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?
14.7 How does an MRO report a split (B) specimen test result to an agency?
14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

**Subpart O—Criteria for Rejecting a Specimen for Testing**

15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?
15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?
15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?
15.4 What discrepancies may require an MRO to cancel a test?

**Subpart P—Laboratory or IITF Suspension/Revocation Procedures**

16.1 When may the HHS certification of a laboratory or IITF be suspended?
16.2 What definitions are used for this subpart?
16.3 Are there any limitations on issues subject to review?
16.4 Who represents the parties?
16.5 When must a request for informal review be submitted?
16.6 What is an abeyance agreement?
16.7 What procedures are used to prepare the review file and written argument?
16.8 When is there an opportunity for oral presentation?
16.9 Are there expedited procedures for review of immediate suspension?
16.10 Are any types of communications prohibited?
16.11 How are communications transmitted by the reviewing official?
16.12 What are the authority and responsibilities of the reviewing official?
16.13 What administrative records are maintained?
16.14 What are the requirements for a written decision?
16.15 Is there a review of the final administrative action?

## Subpart A—Applicability

*Section 1.1 To whom do these Guidelines apply?*

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice

system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.[1]

*Section 1.2 Who is responsible for developing and implementing these Guidelines?*

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

*Section 1.3 How does a federal agency request a change from these Guidelines?*

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

*Section 1.4 How are these Guidelines revised?*

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) The changes will be published in final as a notice in the **Federal Register**.

*Section 1.5 What do the terms used in these Guidelines mean?*

The following definitions are adopted:

*Accessioner.* The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

*Adulterated Specimen.* A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

*Aliquot.* A portion of a specimen used for testing.

*Alternate Responsible Person.* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

*Alternate Responsible Technician.* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible technician is unable to fulfill these obligations.

*Alternate Technology Initial Drug Test.* An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

*Batch.* A number of specimens or aliquots handled concurrently as a group.

*Biomarker.* An endogenous substance used to validate a biological specimen.

*Blind Sample.* A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

*Calibrator.* A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

*Cancelled Test.* The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

*Carryover.* The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

*Certifying Scientist (CS).* The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

*Certifying Technician (CT).* The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

*Chain of Custody (COC) Procedures.* Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

*Chain of Custody Documents.* Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

*Collection Container.* A receptacle used to collect a urine specimen.

*Collection Site.* The location where specimens are collected.

*Collector.* A person trained to instruct and assist a donor in providing a specimen.

*Confirmatory Drug Test.* A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

*Confirmatory Specimen Validity Test.* A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

*Control.* A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

*Cutoff.* The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

*Dilute Specimen.* A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

*Donor.* The individual from whom a specimen is collected.

*Failed to Reconfirm.* The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

*Federal Drug Testing Custody and Control Form (Federal CCF).* The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or,

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that ''incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines . . .'' See 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR 40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

*HHS.* The Department of Health and Human Services.

*Initial Drug Test.* An analysis used to differentiate negative specimens from those requiring further testing.

*Initial Specimen Validity Test.* The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

*Instrumented Initial Test Facility (IITF).* A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

*Invalid Result.* The result reported by an HHS-certified laboratory when the laboratory determines that it cannot complete testing or obtain a valid drug test result.

*Laboratory.* A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

*Limit of Detection.* The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

*Limit of Quantification.* For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

*Lot.* A number of units of an item (*e.g.,* reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

*Medical Review Officer (MRO).* A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

*Negative Result.* The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

*Non-Medical Use of a Drug:* The use of a prescription drug, whether obtained by prescription or otherwise, other than in the manner or for the time period prescribed, or by a person for whom the drug was not prescribed.

*Oral Fluid Specimen.* An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

*Oxidizing Adulterant.* A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

*Performance Testing (PT) Sample.* A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

*Positive Result.* The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmation cutoff concentration.

*Reconfirmed.* The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

*Rejected for Testing.* The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

*Responsible Person (RP).* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

*Responsible Technician (RT).* The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified IITF.

*Sample.* A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

*Secretary.* The Secretary of the U.S. Department of Health and Human Services.

*Specimen.* A sample collected from a donor at the collection site for the purpose of a drug test.

*Split Specimen Collection (for Urine).* A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

*Standard.* Reference material of known purity or a solution containing a reference material at a known concentration.

*Substituted Specimen.* A specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

*Section 1.6 What is an agency required to do to protect employee records?*

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, IITFs, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, is applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *http://www.hhs.gov/ocr/hipaa.*

*Section 1.7 What is a refusal to take a federally regulated drug test?*

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(3) Fail to provide a specimen (*e.g.,* urine or another authorized specimen type) for any drug test required by these Guidelines and authorized by federal agency regulations (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in Sections 8.9 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.5;

(6) Fail or decline to participate in an alternate specimen collection (*e.g.,* oral fluid) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, disrupt the collection process, fail to wash hands after being directed to do so by the collector);

(9) For an observed collection, fail to follow the observer's instructions related to the collection process;

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(11) Admit to the collector or MRO that you have adulterated or (for urine) substituted the specimen.

*Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?*

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, the collector must terminate that portion of the collection process and take action as described in Section 8.9; immediately notify the federal agency's designated representative by any means (*e.g.,* telephone or secure fax machine) that ensures that the refusal notification is immediately received, document the refusal on the Federal CCF, sign and date the Federal CCF, and send all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

**Subpart B—Urine Specimens**

*Section 2.1 What type of specimen may be collected?*

A federal agency may collect urine and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using urine must follow these Guidelines.

*Section 2.2 Under what circumstances may a urine specimen be collected?*

A federal agency may collect a urine specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post-accident test;

(e) Return to duty test; or

(f) Follow-up test.

*Section 2.3 How is each urine specimen collected?*

Each urine specimen is collected as a split specimen as described in Section 2.5.

*Section 2.4 What volume of urine is collected?*

A donor is expected to provide at least 45 mL of urine for a specimen.

*Section 2.5 How does the collector split the urine specimen?*

The collector pours at least 30 mL into a specimen bottle that is designated as A (primary) and then pours at least 15 mL into a specimen bottle that is designated as B (split).

*Section 2.6 When may an entity or individual release a urine specimen?*

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

**Subpart C—Urine Drug and Specimen Validity Tests**

*Section 3.1 Which tests are conducted on a urine specimen?*

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided under Section 3.4;

(b) Is authorized to test each specimen for opiates, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each urine specimen:

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen; and

(4) Perform one or more specimen validity tests for oxidizing adulterants on every specimen.

(d) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

*Section 3.2 May a specimen be tested for additional drugs?*

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory

to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

*Section 3.3 May any of the specimens be used for other purposes?*

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies, specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

*Section 3.4 What are the drug test cutoff concentrations for urine?*

| Initial test analyte | Initial test cutoff (ng/mL) | Confirmatory test analyte | Confirmatory test cutoff concentration (ng/mL) |
|---|---|---|---|
| Marijuana (THCA) [1] | 50 | THCA | 15 |
| Benzoylecgonine | 150 | Benzoylecgonine | 100 |
| Codeine/Morphine | [2] 2000 | Codeine | 2000 |
| | | Morphine | 2000 |
| Hydrocodone/Hydromorphone | [2] 300 | Hydrocodone | 100 |
| | | Hydromorphone | 100 |
| Oxycodone/Oxymorphone | [2] 100 | Oxycodone | 50 |
| | | Oxymorphone | 50 |
| 6-Acetylmorphine | 10 | 6-Acetylmorphine | 10 |
| Phencyclidine | 25 | Phencyclidine | 25 |
| Amphetamine/Methamphetamine | [2] 500 | Amphetamine | 250 |
| | | Methamphetamine | 250 |
| MDMA [3]/MDA [4]/MDEA [5] | [2] 500 | MDMA [3] | 250 |
| | | MDA [4] | 250 |
| | | MDEA [5] | 250 |

[1] Δ-9-Tetrahydrocannabinol-9-carboxylic acid (THCA)

[2] *Immunoassay:* The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

*Alternate technology:* Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[3] Methylenedioxymethamphetamine (MDMA).

[4] Methylenedioxyamphetamine (MDA).

[5] Methylenedioxyethylamphetamine (MDEA).

*Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?*

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* d,l-stereoisomers determination for methamphetamine, tetrahydrocannabivarin, and other specimen validity tests using biomarkers). All tests must meet appropriate validation and quality control requirements.

*Section 3.6 What criteria are used to report a urine specimen as adulterated?*

An HHS-certified laboratory reports a primary (A) specimen as adulterated when:

(a) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the limit of quantitation (LOQ) of the confirmatory test on the second aliquot;

(d) The presence of halogen (*e.g.,* bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or great than 200 mcg/mL nitrite-equivalent cutoff or an equal to or great than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic

immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(f) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in paragraphs (b) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

*Section 3.7 What criteria are used to report a urine specimen as substituted?*

An HHS-certified laboratory reports a primary (A) specimen as substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (*i.e.,* the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (*i.e.,* a refractometer is used to test both aliquots).

*Section 3.8 What criteria are used to report a urine specimen as dilute?*

A dilute result may be reported only in conjunction with the positive or negative drug test results for a specimen.

(a) An HHS-certified laboratory or an HHS-certified IITF reports a primary (A) specimen as dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003 on a single aliquot.

(b) In addition, an HHS-certified laboratory reports a primary (A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

*Section 3.9 What criteria are used to report an invalid result for a urine specimen?*

An HHS-certified laboratory reports a primary (A) specimen as an invalid result when:

(a) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(e) The possible presence of a halogen (*e.g.,* bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(g) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(i) Interference occurs on the immunoassay or alternate technology initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial drug test results cannot be obtained);

(j) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(k) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments; or

(l) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(m) The concentration of a biomarker is not consistent with that established for human urine.

**Subpart D—Collectors**

*Section 4.1 Who may collect a specimen?*

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available.

The hiring official must be a trained collector.

*Section 4.2 Who may not collect a specimen?*

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect his or her own drug testing specimen.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

*Section 4.3 What are the requirements to be a collector?*

(a) An individual may serve as a collector if he or she fulfills the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include one uneventful collection scenario, one insufficient specimen quantity, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen bottle tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are ''error-free.''

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until his or her training as a collector has been properly documented.

*Section 4.4 What are the requirements to be an observer for a direct observed collection?*

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The observer must be the same gender as the donor.

(c) The observer is not required to be a trained collector.

*Section 4.5 What are the requirements to be a trainer for collectors?*

(a) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

*Section 4.6 What must a federal agency do before a collector is permitted to collect a specimen?*

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

**Subpart E—Collection Sites**

*Section 5.1 Where can a collection for a drug test take place?*

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a urine specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.

*Section 5.2 What are the requirements for a collection site?*

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies;

(f) The ability to store records securely; and

(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

*Section 5.3 Where must collection site records be stored?*

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

*Section 5.4 How long must collection site records be stored?*

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

*Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?*

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

*Section 5.6 What are the privacy requirements when collecting a urine specimen?*

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

**Subpart F—Federal Drug Testing Custody and Control Form**

*Section 6.1 What federal form is used to document custody and control?*

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

*Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used for a urine specimen?*

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector uses an incorrect form, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that an incorrect form was used by the collector, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the HHS-certified laboratory or IITF must wait at least 5 business days before the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test.

**Subpart G—Urine Specimen Collection Containers and Bottles**

*Section 7.1 What is used to collect a urine specimen?*

A single-use collection container with a means (*i.e.,* thermometer) to measure urine temperature and two specimen bottles must be used.

*Section 7.2 What are the requirements for a urine collection container and specimen bottles?*

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.

(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.

(c) The two specimen bottles must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

*Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?*

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.

(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).

(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

**Subpart H—Urine Specimen Collection Procedure**

*Section 8.1 What privacy must the donor be given when providing a urine specimen?*

The following privacy requirements apply when a donor is providing a urine specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor. The observer for a direct observed collection (*i.e.,* as described in Section 8.10) must be the same gender as the donor. The monitor for a monitored collection (*i.e.,* as described in Section 8.11) must be the same gender as the donor, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed

stall within a multi-stall restroom or in a single person restroom during a monitored collection.

*Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?*

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (*e.g.,* shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

*Section 8.3 What are the preliminary steps in the urine specimen collection procedure?*

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that he or she is unable to urinate or an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the urine specimen:

(1) The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments; the donor may retain his or her wallet.

(2) The collector asks the donor to empty his or her pockets and display any items that could be used to adulterate or substitute the specimen.

(3) If no items are present that can be used to adulterate or substitute the specimen, the donor can place the items back into his or her pockets and continue the collection procedure.

(4) If an item is present that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, a direct observed collection procedure is used in accordance with Section 8.9. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue the normal collection procedure.

(5) If the donor refuses to show the collector the items in his or her pockets, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

(i) The collector shall instruct the donor to wash and dry his or her hands prior to urination. After washing his or her hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

(1) If the donor refuses to wash his or her hands when instructed by the collector, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

*Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?*

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with Subpart G. The specimen collection container will be opened in view of the donor.

(b) The collector instructs the donor to provide his or her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (*i.e.,* as described in Section 8.10) or a monitored collection (*i.e.,* as described in Section 8.11), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must conduct an immediate collection under direct observation in accordance with Section 8.10. The collector must note the conduct and the fact that the collection was observed on the Federal CCF.

*Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?*

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (*i.e.,* in an area designated by the collector) until the collection is complete. This includes the wait period (*i.e.,* up to 3 hours) if needed to provide a sufficient specimen as described in step (f)(2) below and in Section 8.6.

(b) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash his or her hands and the donor may flush the toilet.

(d) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the

temperature is in the acceptable range of 32°–38 °C/90°–100 °F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) If the temperature of the specimen is outside the range of 32°-38°C/90°-100 °F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.9. The collector will forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF.

(e) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (*e.g.,* unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.10. The collector will forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

(f) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.8.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in paragraphs c and d of this section).

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (*i.e.,* at least 45 mL), the collector proceeds with steps described in Section 8.8.

(iii) If the employee has not provided a sufficient specimen (*i.e.,* at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (d)(2) or (e)(2) above, refuses to provide a second specimen as required in step (f)(2) above, or refuses to provide an alternate specimen as authorized in step (f)(2)(iii) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

*Section 8.6 What procedure is used when the donor states that he or she is unable to provide a urine specimen?*

(a) If the donor states that he or she is unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates his or her inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that he or she could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor is not required to drink any fluids during the 3 hour wait time.

(2) If the donor states that he or she is unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

*Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?*

No, unless the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

*Section 8.8 How does the collector prepare the urine specimens?*

(a) All federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled ''A'' and ''B''. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from him or her. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints his or her name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen. The collector must also send a copy of the Federal CCF to the HHS-certified laboratory or IITF.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: The collector may use excess urine to conduct clinical tests (*e.g.,* protein, glucose) if the collection was conducted in conjunction with a physical examination required by federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

*Section 8.9 When is a direct observed collection conducted?*

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate medical explanation for the result; or

(3) The MRO reported to the agency that the primary bottle (A) specimen was positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be tested and/or the split specimen bottle (B) failed to reconfirm; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range;

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (*e.g.,* abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken);

(3) The collector observes conduct by the donor that indicates a possible attempt to adulterate or substitute the specimen; or

(4) The collector observed materials brought by the donor to the collection site for the purpose of adulterating, substituting, or diluting the specimen.

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

*Section 8.10 How is a direct observed collection conducted?*

A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer must be the same gender as the donor with no exception to this requirement. If there is no collector available of the same gender as the donor, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(a) The observer enters the restroom with the donor;

(b) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(c) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(d) After the donor has completed urinating into the collection container:

(1) If the same person serves as the observer and collector, he or she may receive the collection container from the donor while they are both in the restroom;

(2) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

(e) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(f) The collector then continues with the routine collection procedure in Section 8.3.

*Section 8.11 When is a monitored collection conducted?*

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

*Section 8.12 How is a monitored collection conducted?*

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.9.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, he or she may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.3.

*Section 8.13 How does the collector report a donor's refusal to test?*

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any urine collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

*Section 8.14 What are a federal agency's responsibilities for a collection site?*

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

**Subpart I—HHS Certification of Laboratories and IITFs**

*Section 9.1 Who has the authority to certify laboratories and IITFs to test urine specimens for federal agencies?*

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory or IITF including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory or IITF to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is certified by HHS under these Guidelines to test urine specimens for federal agencies unless it holds such certification.

*Section 9.2 What is the process for a laboratory or IITF to become HHS-certified?*

(a) A laboratory or IITF seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

*Section 9.3 What is the process for a laboratory or IITF to maintain HHS certification?*

(a) To maintain HHS certification, a laboratory or IITF must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

*Section 9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?*

(a) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23, 11.24, 12.20, 12.21, and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

*Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?*

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be less than 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or satisfy the criteria for a substituted specimen, dilute specimen, or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but

are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be between 1.5 and 5.0 or between 8.5 and 12.5;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL; or

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

(c) For each PT cycle, the set of PT samples going to each HHS-certified laboratory or IITF will vary but, within each calendar year, each HHS-certified laboratory or IITF will analyze essentially the same total set of samples.

(d) The laboratory or IITF must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

*Section 9.6 What are the PT requirements for an applicant laboratory?*

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Must not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

*Section 9.7 What are the PT requirements for an HHS-certified urine laboratory?*

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ±50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the

acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

*Section 9.8 What are the PT requirements for an applicant IITF?*

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the three sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the three sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the three sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

*Section 9.9 What are the PT requirements for an HHS-certified IITF?*

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Correctly identify at least 90 percent of the total drug challenges over two consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

*Section 9.10 What are the inspection requirements for an applicant laboratory or IITF?*

(a) An applicant laboratory or IITF is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

*Section 9.11 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?*

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines.

*Section 9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?*

(a) An individual may be selected as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in Subpart K for an HHS-certified laboratory or as a responsible technician as described in Subpart L;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF.

(b) The Secretary or a federal agency may conduct an inspection at any time.

*Section 9.13 What happens if an applicant laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?*

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the laboratory or IITF must start the certification process from the beginning.

*Section 9.14 What happens if an HHS-certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?*

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's or IITF's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory or IITF is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

*Section 9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?*

(a) The Secretary shall revoke certification of an HHS-certified laboratory or IITF in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug and specimen validity test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug and specimen validity tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory or IITF by a federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory or IITF; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory or IITF to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

*Section 9.16 What factors are considered in determining whether to suspend a laboratory's or IITF's HHS certification?*

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

*Section 9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?*

(a) When laboratory's or IITF's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory or IITF with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory or IITF will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

*Section 9.18 May a laboratory or IITF that had its HHS certification revoked be recertified to test federal agency specimens?*

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.17 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for HHS certification as an applicant laboratory or IITF.

*Section 9.19 Where is the list of HHS-certified laboratories and IITFs published?*

(a) The list of HHS-certified laboratories and IITFs is published monthly in the **Federal Register**. This notice is also available on the Internet at *http://www.samhsa.gov/workplace*.

(b) An applicant laboratory or IITF is not included on the list.

**Subpart J—Blind Samples Submitted by an Agency**

*Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories or IITFs?*

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory or IITF that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

*Section 10.2 What are the requirements for blind samples?*

(a) Drug positive blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) A blind sample that is adulterated must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is an adulterated sample at the time of validation.

(d) A blind sample that is substituted must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is a substituted sample at the time of validation.

(e) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

*Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?*

(a) A blind sample must be submitted with the current Federal CCF that the HHS-certified laboratory or IITF uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

*Section 10.4 What happens if an inconsistent result is reported for a blind sample?*

If an HHS-certified laboratory or IITF reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory or IITF reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory or IITF and attempt to determine if the laboratory or IITF made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory or IITF;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

**Subpart K—Laboratory**

*Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?*

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

*Section 11.2 What are the responsibilities of the responsible person (RP)?*

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

*Section 11.3 What scientific qualifications must the RP have?*

The RP must have documented scientific qualifications in analytical toxicology. Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

*Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?*

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

*Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?*

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

*Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?*

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with federally regulated specimens. All training must be documented.

*Section 11.7 What security measures must an HHS-certified laboratory maintain?*

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

*Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?*

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

*Section 11.9 What test(s) does an HHS-certified laboratory conduct on a urine specimen received from an IITF?*

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

*Section 11.10 What are the requirements for an initial drug test?*

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

*Section 11.11 What must an HHS-certified laboratory do to validate an initial drug test?*

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

*Section 11.12 What are the batch quality control requirements when conducting an initial drug test?*

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

*Section 11.13 What are the requirements for a confirmatory drug test?*

(a) The analytical method must use mass spectrometric identification [*e.g.*, gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of a urine specimen when identifying and quantifying drugs or their metabolites.

*Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?*

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

*Section 11.15 What are the batch quality control requirements when conducting a confirmatory drug test?*

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

*Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?*

(a) Each specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results (required specimen validity tests are addressed in Section 11.18); and

(c) Controls must be analyzed concurrently with specimens.

*Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?*

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

*Section 11.18 What are the requirements for conducting each specimen validity test?*

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;

(2) The initial creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL; and

(iii) A control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002;

(iii) One control in the range of 1.004 to 1.018.

(3) For the initial and confirmatory specific gravity tests, the refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a laboratory information management system (LIMS), computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(4) The initial and confirmatory specific gravity tests must have the following calibrators and controls:

(i) A calibrator or control at 1.0000;

(ii) One control targeted at 1.0020;

(iii) One control in the range of 1.0040 to 1.0180; and

(iv) One control equal to or greater than 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 3 to 12 to support the 4 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (*i.e.*, screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) pH screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use;

(4) An initial colorimetric pH test must have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 11;

(iii) One control in the range of 3 to 3.8;

(iv) One control in the range 4.2 to 5;

(v) One control in the range of 5 to 9;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(5) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 3 to 3.8;

(v) One control in the range 4.2 to 5;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(6) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 3 to 3.8; and

(iv) One control in the range 4.2 to 5; and

(7) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(2), (3), or (4) for the compound of interest, a control without the compound of interest (*i.e.*, a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (*i.e.*, certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

*Section 11.19 What are the requirements for an HHS-certified laboratory to report a test result?*

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (h)(1) through (h)(12) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) A primary (A) urine specimen is reported adulterated when:

(1) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.*, multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(4) The presence of halogen (*e.g.*, bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.*, multi-wavelength spectrophotometry, ion chromatography, inductively coupled

plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory method (*e.g.*, GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory method (*e.g.*, GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.*, multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs d(2) through d(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (A) urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory creatinine tests (*i.e.*, the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (*i.e.*, a refractometer is used to test both aliquots) on two separate aliquots.

(f) A primary (A) urine specimen is reported dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) For a specimen that has an invalid result for one of the reasons stated in items (h)(4) through (h)(12) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(h) A primary (A) urine specimen is reported as an invalid result when:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.*, the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.*, multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(5) The possible presence of a halogen (*e.g.*, bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the initial drug tests on two separate aliquots (*i.e.*, valid initial drug test results cannot be obtained);

(10) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments; or

(12) The physical appearances of the A and B specimens are clearly different (note: A is tested).

(i) An HHS-certified laboratory shall reject a primary (A) urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(j) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a urine specimen. For example, a specimen can be positive for a specific drug and adulterated.

(k) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(m) When the concentration of a drug or drug metabolite exceeds the validated

linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(n) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.*, teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(o) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(p) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 11.20 How long must an HHS-certified laboratory retain specimens?*

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of one year.

(b) Retained specimens must be kept in secured frozen storage (−20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the one-year period.

*Section 11.21 How long must an HHS-certified laboratory retain records?*

(a) An HHS-certified laboratory must retain all records generated to support test results for at least two years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.23) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal two-year period of time.

*Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?*

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated;

(13) Number of specimens reported substituted; and

(14) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

*Section 11.23 What HHS-certified laboratory information is available to a federal agency?*

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

*Section 11.24 What HHS-certified laboratory information is available to a federal employee?*

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to his or her drug

test results or a documentation package as described in Section 11.23(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

*Section 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?*

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

*Section 11.26 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?*

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

**Subpart L—Instrumented Initial Test Facility (IITF)**

*Section 12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?*

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified IITF operations. When followed, the SOP manual ensures that all specimens are tested consistently using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for two years.

*Section 12.2 What are the responsibilities of the responsible technician (RT)?*

(a) Manage the day-to-day operations of the HHS-certified IITF even if another individual has overall responsibility for alternate areas of a multi-specialty facility.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified IITF. The RT must ensure the continued competency of IITF personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified IITF, and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RT when procedures are first placed into use or changed or when a new individual assumes responsibility for the management of the HHS-certified IITF. The SOP must be reviewed and documented by the RT annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified IITF in response to the following: Quality control systems not within performance specifications, errors in result reporting or in analysis of performance testing samples, and inspection deficiencies. The RT must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

*Section 12.3 What qualifications must the RT have?*

An RT must:

(a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(b) Have training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF;

(c) Have training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications, as demonstrated by the HHS-certified IITF's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying technician.

*Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?*

(a) HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and qualified to fulfill the responsibilities of the RT.

(1) If an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, business trip), the HHS-certified IITF may continue operations and testing of federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all specimens if the IITF does not have an RT or alternate RT for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RT or alternate RT.

(b) If the RT leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain certification and continue testing federally regulated specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RT's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all federally regulated specimens if the IITF does not have a permanent RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(c) To nominate an individual as the RT or alternate RT, the HHS-certified IITF must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas

and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RT qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified IITF.

(d) The HHS-certified IITF must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RT.

*Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?*

A certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

*Section 12.6 What qualifications and training must other personnel of an HHS-certified IITF have?*

(a) All HHS-certified IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified IITF must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with federally regulated specimens. All training must be documented.

*Section 12.7 What security measures must an HHS-certified IITF maintain?*

(a) An HHS-certified IITF must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for the access to the secured area.

*Section 12.8 What are the IITF chain of custody requirements for specimens and aliquots?*

(a) HHS-certified IITFs must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the IITF through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified IITFs must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

*Section 12.9 What are the requirements for an initial drug test?*

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified IITF must validate an initial drug test before testing specimens;

(c) Initial drug tests must be accurate and reliable for the testing of urine specimens when identifying drugs or their metabolites.

(d) An HHS-certified IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

*Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?*

(a) An HHS-certified IITF must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

*Section 12.11 What are the batch quality control requirements when conducting an initial drug test?*

(a) Each batch of specimens must contain the following calibrators and controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

*Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?*

(a) Each specimen validity test result must be based on performing a single test on one aliquot;

(b) The HHS-certified IITF must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results in accordance with Section 12.14; and

(c) Controls must be analyzed concurrently with specimens.

*Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?*

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

*Section 12.14 What are the requirements for conducting each specimen validity test?*

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on the test;

(2) The creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;
(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;
(iii) A control in the range of 3 mg/dL to 20 mg/dL; and
(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with creatinine test results greater than 5 mg/dL and less than 20 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:
(i) A calibrator or control at 1.000;
(ii) One control targeted at 1.002; and
(iii) One control in the range of 1.004 to 1.018.

(c) The requirements for measuring pH are as follows:

(1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or greater than 9.0.

(2) The pH test must have, at a minimum, the following calibrators and controls:
(i) One control below 4.5;
(ii) One control between 4.5 and 9.0;
(iii) One control above 9.0; and
(iv) One or more calibrators as appropriate for the test. For a pH meter: Calibrators at 4, 7, and 10.

(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,

(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(3), (4), or (6) for the compound of interest, a control without the compound of interest (*i.e.,* a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

*Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?*

(a) An HHS-certified IITF must report a test result to the agency's MRO within an average of 3 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying technician.

(b) A primary (A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.

(d) An HHS-certified IITF shall reject a urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified IITF will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(e) HHS-certified IITFs may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. IITFs and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(f) HHS-certified IITFs must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(g) For rejected specimens, IITFs must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?*

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

*Section 12.17 How long must an HHS-certified IITF retain a specimen?*

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

*Section 12.18 How long must an HHS-certified IITF retain records?*

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years. The IITF may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A federal agency may request the HHS-certified IITF to maintain a documentation package (as described in Section 12.20) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified IITF may retain records other than those included in the documentation package beyond the normal two-year period of time.

*Section 12.19 What statistical summary reports must an HHS-certified IITF provide?*

(a) HHS-certified IITFs must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:
(1) Reporting period (inclusive dates);
(2) HHS-certified IITF name and address;
(3) Federal agency name;

(4) Total number of specimens tested;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test; and

(10) Number of specimens forwarded to an HHS-certified laboratory for testing.

(b) An HHS-certified IITF must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the IITF is performing drug-testing services.

(c) An HHS-certified IITF must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the IITF.

*Section 12.20 What HHS-certified IITF information is available to a federal agency?*

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report from a laboratory, the federal agency may submit a written request for copies of the IITF records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified IITF, and a copy of the electronic report (if any) generated by the HHS-certified IITF;

(4) A brief description of the HHS-certified IITF's drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the résumé or curriculum vitae for the RT and for the certifying technician of record.

*Section 12.21 What HHS-certified IITF information is available to a federal employee?*

A federal employee who is the subject of a drug test may provide a written request through the MRO and/or the federal agency requesting access to any records relating to his or her drug test results or a documentation package (as described in Section 12.20) and any relevant certification, review, or revocation of certification records.

*Section 12.22 What types of relationships are prohibited between an HHS-certified IITF and an MRO?*

An HHS-certified IITF must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified IITF for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified IITF or have any agreement with an HHS-certified IITF that may be construed as a potential conflict of interest.

*Section 12.23 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?*

An HHS-certified IITF can enter into any relationship with an HHS-certified laboratory.

**Subpart M—Medical Review Officer (MRO)**

*Section 13.1 Who may serve as an MRO?*

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs and nonmedical use of prescription drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination, administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

*Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?*

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify and/or train physicians as MROs for federal workplace drug testing programs must submit their qualifications and, if applicable, a sample examination. Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, the course syllabus and materials, documentation that the continuing education courses are accredited by a professional organization, and, if applicable, the delivery method and content of the examination. Each approved MRO training/certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at *http://www.samhsa.gov/workplace/drug-testing*.

*Section 13.3 What training is required before a physician may serve as an MRO?*

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types;

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations), and reporting of results specified by any federal agency for which the individual may serve as an MRO; and

(6) Training in Substance Abuse including information about how to discuss substance misuse and abuse, and how individuals that test positive can access services.

(b) Nationally recognized entities or subspecialty boards that train or certify physicians as MROs should make the MROs aware of prevention and treatment opportunities for individuals after testing positive.

*Section 13.4 What are the responsibilities of an MRO?*

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.19(g) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

*Section 13.5 What must an MRO do when reviewing a urine specimen's test results?*

(a) When the HHS-certified laboratory or HHS-certified IITF reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result for the primary (A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(1) If the recollected specimen provides a negative or negative/dilute result, the MRO reports a negative result to the agency, with no further action required.

(2) If the recollected specimen provides a result other than negative or negative/dilute, the MRO follows the procedures in 13.5(c) through (g) for the recollected specimen.

(c) When the HHS-certified laboratory reports multiple results for the primary (A) urine specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (g) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) urine specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.6(l).

(d) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor. The MRO follows the procedures in Section 13.5(b)(1) or (2) for the recollected specimen.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(e) When the HHS-certified laboratory reports a positive result for opiates for the primary (A) urine specimen, the MRO must determine if there is clinical evidence (in addition to the test result) of illegal use of any opium, or opiates, listed in Schedule I or II of the Controlled Substances Act. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (*i.e.,* the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(f) When an HHS-certified laboratory reports an adulterated or substituted result for the primary (A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a refusal to test to the federal agency because the urine specimen was adulterated or substituted.

(g) When the HHS-certified laboratory reports an invalid result for the primary (A) urine specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, HHS-certified IITF, and/or HHS-certified laboratory to discuss time and temperature issues (*e.g.,* time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0 to 9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the federal agency to immediately collect another urine specimen from the donor using a direct observed collection.

(i) If the specimen collected under direct observation provides a valid

result, the MRO follows the procedures in Section 13.5(a) through (f).

(ii) If the specimen collected under direct observation provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* oral fluid).

(h) When two separate specimens collected during the same testing event were sent to the HHS-certified laboratory for testing (*e.g.,* the collector sent a urine specimen out of temperature range and the subsequently collected specimen—urine or another authorized specimen type), as the MRO, you must follow the verification procedures described in Sections 13.4, 13.5, and 13.6, and:

(1) If both specimens were verified negative, report the result as negative.

(2) If one specimen was verified negative and the other was not (*i.e.,* the specimen was verified as negative/dilute or as positive, adulterated, substituted, and/or invalid), report only the verified result(s) other than negative. For example, if you verified one specimen as negative and the other as a refusal to test because the specimen was substituted, report only the refusal to the federal agency.

(3) If both specimens were verified as positive, adulterated, and/or substituted, report all results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, report the positive and the refusal results to the federal agency.

(4) If one specimen has been verified and the HHS-certified laboratory has not reported the result(s) of the other specimen,

(i) Report verified result(s) of positive, adulterated, or substituted immediately and do not wait to receive the result(s) of the other specimen.

(ii) Do not report a verified result of negative, negative/dilute, or invalid for the first specimen to the federal agency. Hold the report until results of both specimens have been received and verified.

(5) When the HHS-certified laboratory reports an invalid result for one or both specimens, follow the procedures in paragraph c above.

(i) When the HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (*i.e.,* urine).

*Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?*

(a) When another specimen type (*e.g.,* oral fluid) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genitor-urinary matters. Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine and is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* oral fluid) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

*Section 13.7 What happens when an individual is unable to provide a sufficient amount of urine for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?*

(a) This section concerns a situation in which the donor has a medical condition that precludes him or her from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

*Section 13.8 Who may request a test of a split (B) specimen?*

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that he or she has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

*Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?*

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

*Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?*

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or HHS-certified IITF, or have any agreement with the HHS-certified laboratory or the HHS-certified IITF that may be construed as a potential conflict of interest.

**Subpart N—Split Specimen Tests**

*Section 14.1 When may a split (B) specimen be tested?*

(a) The donor may verbally request through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the verbal request after being informed of the result by the MRO. The MRO must document in his or her records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) urine specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another urine specimen from the donor under direct observation, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

*Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?*

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

(c) For a split (B) urine specimen, if the second HHS-certified laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first HHS-certified laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence

of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests as it would conduct on a primary (A) urine specimen and reports those results to the MRO.

*Section 14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?*

(a) An HHS-certified laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (B) urine specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 4 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff concentration of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (*e.g.,* glutaraldehyde, chromium (VI), pyridine, halogens (such as, bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

*Section 14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?*

(a) An HHS-certified laboratory must use the following criteria to reconfirm a substituted result when testing a split (B) urine specimen:

(1) The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 2 mg/dL; and

(2) The specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than or equal to 1.0010 or equal to or greater than 1.0200.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

*Section 14.5 Who receives the split (B) specimen result?*

The second HHS-certified laboratory must report the result to the MRO.

*Section 14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?*

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the primary (A) specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result [specify drug(s)], cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and give the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result [(specify drug(s)]) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [(specify drug(s)]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs,*

*and invalid result.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(l) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and specify adulterant or substituted] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(m) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result [(specify drug(s) and adulterated] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(n) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s) and specify adulterant]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(o) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result [(specify adulterant) and not substituted] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(p) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (specify adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(q) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

*Section 14.7 How does an MRO report a split (B) specimen test result to an agency?*

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

*Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?*

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

**Subpart O—Criteria for Rejecting a Specimen for Testing**

*Section 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?*

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory or IITF must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen; or

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen.

*Section 15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?*

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory or IITF must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory or IITF may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal

CCF, the HHS-certified laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

*Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?*

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory or IITF are considered insignificant and should not cause an HHS-certified laboratory or IITF to reject a urine specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's SSN;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) A ''specimen collection'' box is not marked;

(11) The ''observed'' box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory or IITF copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) The collector failed to check the specimen temperature box and the ''Remarks'' line did not have a comment regarding the temperature being out of range. If, after at least 5 business days, the collector cannot provide a memorandum for record to attest to the fact that he or she did measure the specimen temperature, the HHS-certified laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory or IITF are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist or certifying technician fails to print his or her name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory or IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector, HHS-certified laboratory, or HHS-certified IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

*Section 15.4 What discrepancies may require an MRO to cancel a test?*

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified laboratory or HHS-certified IITF does not contain all the data elements required for the HHS standard laboratory or IITF electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If, after at least 5 business days, the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

**Subpart P—Laboratory or IITF Suspension/Revocation Procedures**

*Section 16.1 When may the HHS certification of a laboratory or IITF be suspended?*

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

*Section 16.2 What definitions are used for this subpart?*

*Appellant.* Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

*Respondent.* Means the person or persons designated by the Secretary in implementing these Guidelines.

*Reviewing Official.* Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing

official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

*Section 16.3 Are there any limitations on issues subject to review?*

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

*Section 16.4 Who represents the parties?*

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

*Section 16.5 When must a request for informal review be submitted?*

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

*Section 16.6 What is an abeyance agreement?*

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

*Section 16.7 What procedures are used to prepare the review file and written argument?*

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

*Section 16.8 When is there an opportunity for oral presentation?*

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting

the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

*Section 16.9 Are there expedited procedures for review of immediate suspension?*

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory or IITF in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

*Section 16.10 Are any types of communications prohibited?*

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

*Section 16.11 How are communications transmitted by the reviewing official?*

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

*Section 16.12 What are the authority and responsibilities of the reviewing official?*

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action

necessary to resolve disputes in accordance with the objectives of these procedures.

*Section 16.13 What administrative records are maintained?*

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

*Section 16.14 What are the requirements for a written decision?*

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

*Section 16.15 Is there a review of the final administrative action?*

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. 2015–11524 Filed 5–13–15; 4:15 pm]

**BILLING CODE 4162–20–P**

# Reader Aids

**Federal Register**

Vol. 80, No. 94

Friday, May 15, 2015

## 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: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

### 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.

**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, MAY

24779–25206 ..... 1
25207–25570 ..... 4
25571–25896 ..... 5
25897–26180 ..... 6
26181–26436 ..... 7
26437–26816 ..... 8
26817–27068 ..... 11
27069–27236 ..... 12
27237–27554 ..... 13
27555–27850 ..... 14
27851–28152 ..... 15

## CFR PARTS AFFECTED DURING MAY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

**3 CFR**

**Proclamations:**
9261 ..... 25571
9262 ..... 25573
9263 ..... 25575
9264 ..... 25577
9265 ..... 25579
9266 ..... 25889
9267 ..... 25891
9268 ..... 25893
9269 ..... 25895
9270 ..... 26177
9271 ..... 26179
9272 ..... 26433
9273 ..... 26435
9274 ..... 26817
9275 ..... 27235
9276 ..... 27237
9277 ..... 27239
9278 ..... 27241
9279 ..... 27849

**Administrative Orders:**
Memorandums:
Memorandum of April 16, 2015 ..... 25207
Memorandum of April 29, 2015 ..... 27555
Notices:
Notice of May 6, 2015 ..... 26815
Notice of May 8, 2015 ..... 27067
Notice of May 13 2015 ..... 27851

**5 CFR**

2418 ..... 24779

**7 CFR**

Ch. 0 ..... 25901
205 ..... 25897
210 ..... 26181
235 ..... 26181
925 ..... 27243
985 ..... 27245
4284 ..... 26788

**Proposed Rules:**
210 ..... 26846
215 ..... 26846
220 ..... 26846
235 ..... 26846
319 ..... 24838
900 ..... 25969
1218 ..... 26469

**9 CFR**

107 ..... 26819
417 ..... 27557

**Proposed Rules:**
3 ..... 24840
309 ..... 27269

**10 CFR**

**Proposed Rules:**
50 ..... 25237
430 ..... 26198
431 ..... 24841, 26199, 26475, 27601

**12 CFR**

620 ..... 26822
701 ..... 25924
704 ..... 25932
1207 ..... 25209
1806 ..... 25581

**Proposed Rules:**
704 ..... 27108
745 ..... 27109

**13 CFR**

**Proposed Rules:**
127 ..... 24846

**14 CFR**

Ch. I ..... 27853
39 ..... 24789, 24791, 25589, 25591, 27069, 27072, 27074, 27077, 27081
71 ..... 24793, 27563
91 ..... 26822
97 ..... 25594, 25595
121 ..... 25215
135 ..... 25215

**Proposed Rules:**
39 ..... 24850, 24852, 24854, 24856, 25247, 25249, 25254, 25627, 25630, 26484, 26487, 26490, 26492, 27114, 27116, 27601, 27605, 27607
71 ..... 24858, 24860, 24861, 26496, 26497, 26870, 26872, 27119

**15 CFR**

30 ..... 27853

**Proposed Rules:**
4 ..... 26499
734 ..... 25798
740 ..... 25798
742 ..... 25798
744 ..... 25798
772 ..... 25798
774 ..... 25798

**16 CFR**

3 ..... 25940
4 ..... 25940
1120 ..... 25216

**17 CFR**

**Proposed Rules:**
32 ..... 26200
229 ..... 26330
240 ..... 26330, 27444

242 ....27444

**18 CFR**

**Proposed Rules:**
352 ....25633

**19 CFR**

181 ....26828

**20 CFR**

**Proposed Rules:**
655 ....25633

**21 CFR**

890 ....25226
1308 ....27854
**Proposed Rules:**
310 ....25166
1308 ....27611

**22 CFR**

51 ....27856
**Proposed Rules:**
121 ....25821

**24 CFR**

91 ....25901
93 ....25901

**25 CFR**

226 ....26994

**26 CFR**

1 ....25230, 26437
53 ....25230
602 ....25230
**Proposed Rules:**
1 ....25970, 26500, 26873

**29 CFR**

1926 ....25366
4022 ....27857

**30 CFR**

1206 ....24794
1210 ....24794

**32**

320 ....25230
**Proposed Rules:**
2002 ....26501

**33 CFR**

100 ....27086, 27087, 27858
117 ....24814, 24815, 25232, 25233, 25598, 26182, 26183, 26442, 27099, 27563
165 ....24816, 25599, 26443, 26445, 27087, 27100, 27565
**Proposed Rules:**
100 ....27616
117 ....27619
147 ....24863, 25256
165 ....24866, 24869, 25634, 26511, 26514

**34 CFR**

Ch. III ....26830
Ch. VI ....27036
**Proposed Rules:**
Ch. III ....27868, 27874

**36 CFR**

**Proposed Rules:**
1192 ....27275

**38 CFR**

63 ....24819
77 ....25233
**Proposed Rules:**
17 ....27878

**39 CFR**

20 ....26447
111 ....25528
**Proposed Rules:**
3001 ....26517

**40 CFR**

9 ....26448
49 ....25068
52 ....24821, 26183, 26189, 26461, 27102, 27251, 27255
80 ....26191, 26463
174 ....25601, 25943, 25946
180 ....24824, 25950, 25953
300 ....27859
450 ....25235
721 ....26448
**Proposed Rules:**
52 ....24872, 24874, 26210, 27121, 27127, 27275, 27276
80 ....26212
81 ....24874
300 ....27883
704 ....26518
745 ....27621
1600 ....27276

**41 CFR**

300–3 ....27259
301–10 ....27259
301–70 ....27259

**42 CFR**

37 ....27862
86 ....26464
121 ....26464
423 ....25958
**Proposed Rules:**
412 ....25012, 25637
418 ....25832

**43 CFR**

**Proposed Rules:**
2 ....27623
47 ....27134
48 ....27134

**44 CFR**

64 ....24830, 27261
67 ....27567, 27570

**45 CFR**

1355 ....27263
**Proposed Rules:**
98 ....25260
170 ....25637
1206 ....25637
1210 ....25637
1211 ....25637
1216 ....25637
1217 ....25637
1218 ....25637
1220 ....25637
1222 ....25637
1226 ....25637
2556 ....25637

**47 CFR**

1 ....27572
2 ....27107
73 ....27572
74 ....27862
90 ....25604
**Proposed Rules:**
1 ....27626
20 ....25977
36 ....25989
42 ....25989
54 ....25989
63 ....25989
64 ....25989

**48 CFR**

Ch. 1 ....26422, 26429
1 ....26423
4 ....26427
15 ....26424
22 ....26423, 26427
39 ....26427
42 ....26426
52 ....26423, 26427
1328 ....27266
1352 ....27266
**Proposed Rules:**
1 ....26883
2 ....26883
7 ....26883
11 ....26883
23 ....26883
25 ....26883
52 ....26883
501 ....25994
516 ....25994
538 ....25994
552 ....25994
1823 ....26519
1842 ....27278
1846 ....26519
1852 ....26519, 27278

**49 CFR**

27 ....26196
37 ....26196
171 ....26644
172 ....26644
173 ....26644
174 ....26644
179 ....26644
**Proposed Rules:**
391 ....25260
Ch. X ....27281
1300 ....27280
1313 ....27280

**50 CFR**

10 ....26467
86 ....26150
402 ....26832
622 ....24832, 25966
635 ....24836, 25609, 26196, 27863
648 ....25110, 25143, 25160
660 ....25611, 27588
679 ....25625, 25967
**Proposed Rules:**
223 ....25272
224 ....25272
648 ....25656

## LIST OF PUBLIC LAWS

**Note:** No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

**Last List May 4, 2015**

## 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.