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9 a.m.-12:30 p.m.

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Contents

Federal Register

Vol. 75, No. 199

Friday, October 15, 2010

Actuaries, Joint Board for Enrollment

See Joint Board for Enrollment of Actuaries

Agency for Healthcare Research and Quality

NOTICES

Meetings:

- National Advisory Council for Healthcare Research and Quality, 63497–63498
- Patient Safety Organizations Voluntary Delisting, 63498–63499

Agriculture Department

See Food Safety and Inspection Service

See Foreign Agricultural Service

See Forest Service

Army Department

See Engineers Corps

Arts and Humanities, National Foundation

See National Foundation on the Arts and the Humanities

Blind or Severely Disabled, Committee for Purchase From People Who Are

See Committee for Purchase From People Who Are Blind or Severely Disabled

Bureau of Ocean Energy Management, Regulation and Enforcement

RULES

Safety and Environmental Management Systems:
Oil and Gas and Sulphur Operations in Outer Continental Shelf, 63610–63654

NOTICES

Environmental Impact Statements; Availability, etc.:
Outer Continental Shelf, Alaska OCS Region, Chukchi Sea Planning Area, Oil and Gas Lease 193 Sale, 63504–63505

Centers for Disease Control and Prevention

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63485–63486

Meetings:

- Advisory Council for the Elimination of Tuberculosis, 63496
- Partnerships to Advance the National Occupational Research Agenda, 63495–63496

Centers for Medicare & Medicaid Services

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63482–63485

Delegation of Authorities, 63480

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Child Care and Development Block Grant Reporting Requirements, 63488

Coast Guard

RULES

Drawbridge Operation Regulations:
Hackensack River, Jersey City, NJ, 63398–63399

Commerce Department

See Foreign-Trade Zones Board

See International Trade Administration

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63438–63439

Committee for Purchase From People Who Are Blind or Severely Disabled

NOTICES

Procurement List; Additions and Deletions, 63446–63447

Defense Department

See Engineers Corps

RULES

Civilian Health and Medical Program of the Uniformed Services:

- Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, 63383–63398

Department of Transportation

See Pipeline and Hazardous Materials Safety Administration

Employment and Training Administration

NOTICES

Amended Certifications Regarding Eligibility To Apply for Worker Adjustment Assistance:

- Propex Operating Company, LLC, Bainbridge, GA, 63508
- Warner Chilcott Pharmaceuticals, Inc., Norwich, NY, 63508–63509
- Hewlett Packard – Enterprise Business Services, et al., Pontiac, MI, 63509

Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance, 63509–63512

Investigations Regarding Certifications of Eligibility to

Apply for Worker Adjustment Assistance, 63512–63513

Revised Determinations on Reconsideration:

- Modine Manufacturing Co., Pemberville, OH, 63513

Energy Department

See Federal Energy Regulatory Commission

PROPOSED RULES

Fossil Fuel-Generated Energy Consumption Reduction for New Federal Buildings and Major Renovations of

Federal Buildings, 63404–63419

NOTICES

Meetings:

- DOE/NSF High Energy Physics Advisory Panel, 63450

Engineers Corps**NOTICES**

Environmental Impact Statements; Availability, etc.:
 Medium Diversion with Dedicated Dredging at Myrtle Grove Feasibility Study, Plaquemines Parish, LA, 63447–63448
 Sunridge Properties, Sunridge Specific Plan Area, Rancho Cordova, Sacramento County, CA, 63448–63449

Meetings:
 Chief of Engineers Environmental Advisory Board, 63449

Environmental Protection Agency**NOTICES**

Environmental Impact Statements; Availability, etc.:
 Weekly Receipt, 63469–63470

Meetings:
 FIFRA Scientific Advisory Panel; Cancellation, 63470
 National and Governmental Advisory Committees to U.S. Representative to Commission for Environmental Cooperation, 63470–63471

Teleconference:
 Clean Air Scientific Advisory Committee, 63471–63472

Equal Employment Opportunity Commission**NOTICES**

SES Performance Review Board; Appointment of Members, 63472

Executive Office of the President

See Presidential Documents

Federal Aviation Administration**PROPOSED RULES**

Airworthiness Directives:
 Bombardier, Inc. Model BD 700 1A10 and BD 700 1A11 Airplanes, 63420–63422
 Embraer; Empresa Brasileira de Aeronautica S.A. Model EMB–500 Airplanes, 63422–63424
 Flightcrew Member Duty and Rest Requirements, 63424–63425

NOTICES

Meetings:
 Special Committee 222; Inmarsat Aeronautical Mobile Satellite (Route) Services, 63534–63535

Request For Public Comment:
 Morgantown Municipal Airport, Morgantown, WV, 63540

Federal Communications Commission**RULES**

FM Table of Allotments:
 Culebra, Puerto Rico, Charlotte Amalie and Christiansted, Virgin Islands, 63402

PROPOSED RULES

Radio Broadcasting Services:
 Willow Creek, CA, 63431–63432

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63472–63475
 Petitions for Reconsideration of Action in Rulemaking Proceeding, 63475
 Radio Broadcasting Services:
 AM or FM Proposals To Change The Community of License, 63475–63476

Federal Emergency Management Agency**RULES**

Suspensions of Community Eligibility, 63399–63402

NOTICES

Major Disaster Declarations:
 Illinois; Amendment No. 3, 63500
 Iowa; Amendment No. 10, 63500
 Major Disasters and Related Determinations:
 Virgin Islands, 63500–63501

Federal Energy Regulatory Commission**NOTICES**

Applications:
 ANR Pipeline Co., 63451–63452
 Wilkesboro Hydroelectric Co., 63450–63451

Baseline Filings:
 Lobo Pipeline Company LP, 63452
 ONEOK Gas Storage, L.L.C., 63452

Combined Filings, 63452–63462
 Docket Designation for Smart Grid Interoperability Standards, 63462

Environmental Assessments; Availability, etc.:
 MARC I Hub Line Project, Central New York Oil and Gas Co., LLC, 63462–63465

Filings:
 Hill-Lake Gas Storage, LLC, 63465

Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
 Ashtabula Wind III, LLC, 63466
 LSP Safe Harbor Holdings, LLC, 63465–63466

Market-Based Rate Filings:
 Flat Water Wind Farm, LLC, 63466

Petitions:
 Sawgrass Storage LLC, 63466–63467

Preliminary Permit Applications:
 Lanai Hydro, LLC, 63467–63468

Records Governing Off-the-Record Communications, 63468
 Revocation of Market-Based Rate Tariffs:
 BM2 LLC, DJGW LLC, 63468–63469

Staff Attendances:
 Southwest Power Pool Regional State Committee, etc., 63469

Federal Highway Administration**NOTICES**

Environmental Impact Statements; Availability, etc.:
 Cameron County; TX, 63533–63534

Federal Maritime Commission**NOTICES**

Ocean Transportation Intermediary License; Applicants, 63476

Federal Motor Carrier Safety Administration**NOTICES**

Qualification of Drivers; Exemption Applications; Diabetes Mellitus, 63536–63540

Federal Railroad Administration**NOTICES**

Petitions for Waivers of Compliance, 63535–63536

Federal Trade Commission**PROPOSED RULES**

Guides for Use of Environmental Marketing Claims:
 Proposed Revisions to Guidelines, 63552–63607

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63476–63478

Financial Crimes Enforcement Network**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Bank Secrecy Act Suspicious Activity Report Database Proposed Data Fields, 63545–63550

Fish and Wildlife Service**NOTICES**

Comprehensive Conservation Plans and Environmental Assessments:
Sonny Bono Salton Sea National Wildlife Refuge Complex, Imperial and Riverside Counties, CA, 63502–63503

Final Comprehensive Conservation Plans and Findings of No Significant Impact:
Crane Meadows National Wildlife Refuge, Morrison County, MN, 63505

Food and Drug Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Product Jurisdiction; Assignment of Agency Component for Review of Premarket Applications, 63489

Food Safety and Inspection Service**NOTICES**

Committee Reestablishment:
National Advisory Committee on Microbiological Criteria for Foods, 63433–63434

Compliance Guides; Availability, etc.:
Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments, 63434

Foreign Agricultural Service**NOTICES**

Trade Adjustment Assistance for Farmers, 63437–63438

Foreign-Trade Zones Board**NOTICES**

Site Renumberings:
Foreign-Trade Zone 86, Tacoma, WA, 63445

Forest Service**NOTICES**

Environmental Impact Statements; Availability, etc.:
Grizzly Vegetation and Transportation Management Project, Kootenai National Forest; Lincoln County, MT, 63434–63436

Meetings:
Del Norte Resource Advisory Committee, 63437
Glenn/Colusa County Resource Advisory Committee, 63436–63437
Nevada and Placer Counties Resource Advisory Committee, 63436
West Virginia Resource Advisory Committee, 63436

Health and Human Services Department

See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Children and Families Administration
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

RULES

Countermeasures Injury Compensation Program; Administrative Implementation, 63656–63688

NOTICES

5th Annual PHEMCE Stakeholders Workshop and BARDA Industry Day, 63478

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63478–63480

Delegation of Authorities, 63480

Medicaid Program:
Implementation of Section 614 of the Children's Health Insurance Program Reauthorization Act of 2009, etc., 63480–63482

Homeland Security Department

See Coast Guard
See Federal Emergency Management Agency
See Transportation Security Administration

Housing and Urban Development Department**NOTICES**

Buy American Exceptions under the American Recovery and Reinvestment Act of 2009, 63501

Federal Property Suitable as Facilities to Assist Homeless, 63501–63502

Interior Department

See Bureau of Ocean Energy Management, Regulation and Enforcement
See Fish and Wildlife Service
See Land Management Bureau
See National Indian Gaming Commission
See National Park Service

Internal Revenue Service**RULES**

Exclusions From Gross Income of Foreign Corporations; Correction, 63380

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63541–63545

International Trade Administration**NOTICES**

Extension of Final Results of Antidumping Duty Administrative Reviews:
Certain Welded Carbon Steel Standard Pipes and Tubes from India, 63439–63440

Extension of Preliminary Results of Antidumping Duty New Shipper Reviews:
Wooden Bedroom Furniture from People's Republic of China; Correction, 63440

Extension of Time for Final Results of Antidumping Duty Administrative Reviews:
Pure Magnesium from the People's Republic of China, 63440

Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Reviews:
Certain Preserved Mushrooms from People's Republic of China, 63440–63441

Rescission of Antidumping Duty Administrative Reviews:
Glycine from People's Republic of China, 63444–63445

Joint Board for Enrollment of Actuaries**NOTICES**

Renewal of Advisory Committee on Actuarial Examinations, 63505–63506

Justice Department**NOTICES**

Lodging of Consent Decrees under the Clean Air Act, Clean Water Act, et al., 63506

Labor Department

See Employment and Training Administration
See Occupational Safety and Health Administration
See Workers Compensation Programs Office

Land Management Bureau**NOTICES**

Environmental Impact Statements; Availability, etc.:
Solar Millennium; Amargosa Farm Road Solar Power Project; Nye County, NV, 63503–63504

Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation**NOTICES**

Meetings; Sunshine Act, 63513–63514

National Credit Union Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63514

National Foundation on the Arts and the Humanities**NOTICES**

Meetings:
Arts Advisory Panel, National Endowment for the Arts, 63516
Humanities Panel, 63514–63516
Meetings; Sunshine Act, 63516–63517

National Indian Gaming Commission**NOTICES**

Environmental Impact Statements; Availability, etc.:
Federated Indians of the Graton Rancheria Casino and Hotel, Sonoma County, CA, 63517

National Institute of Standards and Technology**NOTICES**

Prospective Grant of Exclusive Patent License, 63443–63444

National Institutes of Health**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Multi-Ethnic Study of Atherosclerosis Event Surveillance, 63488–63489
National Epidemiologic Survey on Alcohol and Related Conditions – III, 63490–63491
NIH Office of Intramural Training & Education Application, 63489–63490

Meetings:

Center for Scientific Review, 63492, 63494
Eunice Kennedy Shriver National Institute of Child & Human Development, 63498
National Cancer Institute, 63493–63495
National Center for Complementary and Alternative Medicine, 63498
National Institute of Arthritis and Musculoskeletal and Skin Diseases, 63492–63493, 63496
National Institute of Diabetes and Digestive and Kidney Diseases, 63495
National Institute of General Medical Sciences, 63493, 63497
National Institute on Aging, 63497

National Institute on Alcohol Abuse and Alcoholism, 63494

National Institute on Drug Abuse, 63491–63492, 63498
Office of the Director; National Institutes of Health, 63493

National Oceanic and Atmospheric Administration**RULES**

Fisheries of the Exclusive Economic Zone Off Alaska: Pacific Cod by Vessels Catching for Processing by the Inshore Component in the Western Regulatory Area of the Gulf of Alaska, 63402–63403

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
NOAA Teacher at Sea Alumni Survey, 63439
Interagency Ocean Observation Committee Proposed Certification Design Process; Availability, 63441
Meetings:
Marine Protected Areas, 63443
Pacific Fishery Management Council, 63441–63443
Vessel Monitoring Systems:
Approved Mobile Transmitting Units and Communications Service Providers in Fisheries of Western and Central Pacific, 63445–63446

National Park Service**PROPOSED RULES**

Historic Preservation Certifications for Federal Income Tax Incentives, 63428–63431

National Science Foundation**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 63517–63518

Nuclear Regulatory Commission**NOTICES**

Environmental Assessments and Findings of No Significant Impact; Availability:
License Amendment No. 61 for Rio Algom Mining LLC; Ambrosia Lake, NM, 63518–63519
Environmental Assessments; Availability, etc.:
Proposed License Renewal, Nuclear Fuel Services, Inc., Erwin, TN, 63519–63521
Environmental Impact Statements; Availability, etc.:
PSEG Power, LLC and PSEG Nuclear, LLC; Permit Application, 63521–63523

Occupational Safety and Health Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Logging Operations, 63506–63508

Pension Benefit Guaranty Corporation**RULES**

Benefits Payable in Terminated Single-Employer Plans: Interest Assumptions for Paying Benefits, 63380–63382

Personnel Management Office**NOTICES**

Excepted Service Appointments, 63523–63524

Pipeline and Hazardous Materials Safety Administration**NOTICES**

Meetings:
International Standards on the Transport of Dangerous Goods, 63534

Presidential Documents**PROCLAMATIONS**

Special Observances:

- Columbus Day (Proc. 8584), 63693–63694
- National School Lunch Week (Proc. 8583), 63689–63692

Railroad Retirement Board**NOTICES**

Computer Matching and Privacy Protection Act of 1988:
Report of Matching Program; RRB and State Medicare
Agencies, 63524–63525

Securities and Exchange Commission**NOTICES**

Orders of Suspension of Trading:
Camera Platforms International, Inc.; Castleguard Energy,
Inc.; CD Warehouse, Inc. et al., 63526

Self-Regulatory Organizations; Proposed Rule Changes:
BATS Y-Exchange, Inc., 63528–63530
NASDAQ OMX PHLX LLC, 63526–63528
NYSE Arca, Inc., 63530–63532

Small Business Administration**PROPOSED RULES**

Surety Bond Guarantee Program; Timber Sales, 63419–
63420

NOTICES

Meetings:
Audit and Financial Management Advisory, 63525–63526

State Department**NOTICES**

Designation of Armed Islamic Group and All Associated
Aliases as a Foreign Terrorist Organization, 63532

Substance Abuse and Mental Health Services Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 63486–63488

Surface Transportation Board**NOTICES**

Acquisition and Operation Exemptions:
Lancaster and Chester Railroad, LLC, Lancaster & Chester
Railway Co., 63532–63533

Continuance in Control Exemptions:
Gulf and Ohio Railways Holding Co., Inc., et al., 63533

Trackage Rights Exemptions:
Norfolk Southern Railway Co.; Illinois Central Railroad
Co., 63540–63541

Transportation Department

See Federal Aviation Administration
See Federal Highway Administration
See Federal Motor Carrier Safety Administration
See Federal Railroad Administration
See Pipeline and Hazardous Materials Safety
Administration

See Surface Transportation Board
See Transportation Security Administration

Transportation Security Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Sensitive Security Information Threat Assessments,
63499–63500

Treasury Department

See Financial Crimes Enforcement Network
See Internal Revenue Service

RULES

Financial Crimes Enforcement Network:
Amendment to the Bank Secrecy Act Regulations;
Defining Mutual Funds as Financial Institutions,
63382–63383

NOTICES

Meetings:
Debt Management Advisory Committee, 63541

Workers Compensation Programs Office**RULES**

Technical Amendment, 63379–63380

PROPOSED RULES

Regulations implementing the Longshore and Harbor
Workers' Compensation Act:
Recreational Vessels, 63425–63428

Separate Parts In This Issue**Part II**

Federal Trade Commission, 63552–63607

Part III

Interior Department, Bureau of Ocean Energy Management,
Regulation and Enforcement, 63610–63654

Part IV

Health and Human Services Department, 63656–63688

Part V

Presidential Documents, 63689–63694

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.

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settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR**Proclamations:**

8583.....63691
8584.....63693

10 CFR**Proposed Rules:**

433.....63404
435.....63404

13 CFR**Proposed Rules:**

115.....63419

14 CFR**Proposed Rules:**

39 (2 documents)63420,
63422
117.....63424
121.....63424

16 CFR**Proposed Rules:**

260.....63552

20 CFR

Ch. VI.....63379

Proposed Rules:

701.....63425

26 CFR

1.....63380

29 CFR

4022.....63380

30 CFR

250.....63610

31 CFR

103.....63382

32 CFR

199.....63383

33 CFR

117.....63398

36 CFR**Proposed Rules:**

67.....63428

42 CFR

110.....63656

44 CFR

64.....63399

47 CFR

73.....63402

Proposed Rules:

73.....63431

50 CFR

679.....63402

Rules and Regulations

Federal Register

Vol. 75, No. 199

Friday, October 15, 2010

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.

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DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Chapter VI

RIN 1290-AA24

Technical Amendment

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor is revising its regulations to reflect the Secretary's delegation of authority to administer the Longshore and Harbor Workers Compensation Act and its extensions (LHWCA) and the Black Lung Benefits Act (BLBA) to the Director, Office of Workers' Compensation Programs (OWCP). This authority previously resided with the Employment Standards Administration (ESA), which has now been dissolved.

DATES: Effective October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Shelby Hallmark, Director, Office of Workers' Compensation Programs, U.S. Department of Labor, Room S-3524, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693-0031 (this is not a toll-free number). TTY/TDD callers may dial toll free 1-800-877-8339 for further information.

SUPPLEMENTARY INFORMATION:

I. Background of This Rulemaking

Prior to November 8, 2009, the Secretary had delegated her statutory authority to administer the LHWCA and the BLBA to the Assistant Secretary for the Employment Standards Administration. Secretary's Order 13-71, 36 FR 8755 (May 12, 1971). The Assistant Secretary, in turn, delegated authority to administer both programs to OWCP, one of ESA's sub-agencies.

On November 8, 2009, the Secretary dissolved ESA into its constituent

components. See Secretary's Order 10-2009, 74 FR 58834 (Nov. 13, 2009). The Secretary then delegated her authority to administer the LHWCA and the BLBA directly to the Director, OWCP. *Id.* The changes made by this rule simply reflect this administrative reorganization and do not change any substantive rule governing administration of these statutes.

II. Summary of the Rule

A. Revision of 20 CFR Chapter VI Heading

This rule revises the heading of 20 CFR chapter VI, which contains regulations governing the administration of the LHWCA and the BLBA. (A full list of citations for the statutes addressed by 20 CFR chapter VI is set forth at 20 CFR 701.101.) The rule replaces the title "Employment Standards Administration, Department of Labor" with "Office of Workers' Compensation Programs, Department of Labor." The heading change reflects the abolition of ESA and the Secretary's current delegation of administrative authority over the LHWCA and the BLBA to OWCP.

B. Section 701.201 Office of Workers' Compensation Programs

This rule has been revised to remove references and cross-references to the now-dissolved ESA and to clarify the Secretary's delegation of authority for the administration of the LHWCA and the BLBA to OWCP.

III. Statutory Authority

Section 39(a) of the LHWCA (33 U.S.C. 939(a)) and sections 411(b) and 426(a) of the BLBA (30 U.S.C. 921(b) and 936(a)); 5 U.S.C. 301 (Departmental Regulations); 29 U.S.C. 551 *et seq.* (Establishment of Department; Secretary; Seal); and Reorganization Plan No. 6 1950 (5 U.S.C. App. 1 Reorg. Plan 6 1950) authorize the Secretary of Labor to prescribe rules and regulations necessary for the administration and enforcement of the LHWCA and the BLBA.

IV. Rulemaking Analyses

Administrative Procedure Act

Section 553 of the Administrative Procedure Act (APA) exempts "rules of agency organization, procedure, or practice" from proposed rulemaking (*i.e.*, notice-and-comment rulemaking).

5 U.S.C. 553(b)(3)(A). Rules are also exempt when an agency finds "good cause" that notice and comment rulemaking procedures would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(3)(B). An agency may similarly make the rule effective upon publication when it determines that delaying the effective date of the rule, as normally required by 5 U.S.C. 553, is unnecessary and good cause exists to make the rule effective immediately. 5 U.S.C. 553(d)(3).

Here, the Department has determined that this rulemaking meets the notice-and-comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (b)(3)(B). The Department's revisions to the 20 CFR chapter VI heading and § 701.201 pertain solely to the delegation of administrative authority within the Department, and do not alter any substantive standard. The Department does not believe public comment is necessary for these minor revisions. For these reasons, the Department also finds that good cause exists under 5 U.S.C. 553(d)(3) to make the revisions effective immediately upon publication in the **Federal Register**.

Regulatory Flexibility Act

Because the Department has concluded that this action is not subject to the Administrative Procedure Act's proposed rulemaking requirements, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

This action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate (2 U.S.C. 1531 *et seq.*).

Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Executive Order 12866

This action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735 (Oct. 4, 1993)).

Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The 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."

Executive Order 12988 (Civil Justice Reform)

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

List of Subjects in 20 CFR Part 701

Longshore and harbor workers, Organization and functions (government agencies), Workers' compensation.

Based on the authority and reasons set forth in the preamble, 20 CFR chapter VI is amended to read as follows:

CHAPTER VI—OFFICE OF WORKERS' COMPENSATION PROGRAMS, DEPARTMENT OF LABOR

1. Revise the chapter heading of 20 CFR chapter VI to read as shown above.

PART 701—GENERAL; ADMINISTERING AGENCY; DEFINITIONS AND USE OF TERMS

2. The authority citation for part 701 is revised to read as follows:

Authority: 5 U.S.C. 301 and 8171 et seq.; 33 U.S.C. 939; 36 D.C. Code 501 et seq.; 42 U.S.C. 1651 et seq.; 43 U.S.C. 1331; Reorganization Plan No. 6 of 1950, 15 FR 3174, 3 CFR, 1949–1953 Comp., p. 1004, 64 Stat. 1263; Secretary's Order 10–2009, 74 FR 58834 (Nov. 13, 2009).

3. Revise § 701.201 to read as follows:

§ 701.201 Office of Workers' Compensation Programs.

The Office of Workers' Compensation Programs is responsible for administering the LHWCA and its extensions.

Signed at Washington, DC, this 5th day of October 2010.

Seth D. Harris,

Deputy Secretary.

[FR Doc. 2010–25521 Filed 10–14–10; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9502]

RIN 1545–BF90

Exclusions From Gross Income of Foreign Corporations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9502) that were published in the Federal Register on Friday, September 17, 2010 (75 FR 56858) under section 883(a) and (c) of the Internal Revenue Code, concerning the exclusion from gross income of income derived by certain foreign corporations from the international operation of ships or aircraft.

DATES: This correction is effective on October 15, 2010, and is applicable on September 17, 2010.

FOR FURTHER INFORMATION CONTACT: Patricia A. Bray, (202) 622–3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9502) that are the subject of this document are under section 883 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9502) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.883–2 is amended by revising paragraph (f)(4)(ii)(C) to read as follows:

§ 1.883–2 Treatment of publicly-traded corporations.

* * * * *

(f) * * *
(4) * * *
(ii) * * *

(C) The number of days during the taxable year of the foreign corporation that such qualified shareholders owned, directly or indirectly, their shares in the closely held block of stock.

* * * * *

Par. 3. Section 1.883–5 is amended by revising the heading of paragraph (d) to read as follows:

§ 1.883–5 Effective/applicability dates.

* * * * *

(d) Effective/applicability dates.

* * *

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2010–25950 Filed 10–14–10; 8:45 am]

BILLING CODE 4830–01–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 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 November 2010. Interest assumptions are also published on PBGC's Web site (http://www.pbgc.gov).

DATES: Effective November 1, 2010.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, 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.

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 November 2010.¹

The November 2010 interest assumptions under the benefit payments regulation will be 1.75 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 assumptions in effect for October 2010, 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 November 2010, 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 205, 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 |
| * | * | * | * | * | * | * | * | * |
| 205 | 11-1-10 | 12-1-10 | 1.75 | 4.00 | 4.00 | 4.00 | 7 | 8 |

■ 3. In appendix C to part 4022, Rate Set 205, 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 |
| * | * | * | * | * | * | * | * | * |
| 205 | 11-1-10 | 12-1-10 | 1.75 | 4.00 | 4.00 | 4.00 | 7 | 8 |

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.

Issued in Washington, DC, on this 12th day of October 2010.

Vincent K. Snowbarger,

Deputy Director for Operations, Pension Benefit Guaranty Corporation.

[FR Doc. 2010-26081 Filed 10-14-10; 8:45 am]

BILLING CODE 7709-01-P

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506-AA93

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations; Defining Mutual Funds as Financial Institutions; Extension of Compliance Date

AGENCY: Financial Crimes Enforcement Network (“FinCEN”), Treasury.

ACTION: Final rule; extension of compliance date.

SUMMARY: FinCEN is issuing this final rule extending the compliance date for those provisions in 31 CFR 103.33 that apply to mutual funds. On April 14, 2010, FinCEN issued a final rule that included mutual funds within the general definition of “financial institution” in regulations implementing the Bank Secrecy Act (“BSA”). The final rule subjects mutual funds to 31 CFR 103.33, which requires the creation, retention, and transmittal of records or information for transmittals of funds. FinCEN is extending, from January 10, 2011 to April 10, 2011, the date on which mutual funds must begin to comply with 31 CFR 103.33.

DATES: This final rule is effective on October 15, 2010. The compliance date for 31 CFR 103.33 is extended from January 10, 2011 to April 10, 2011.

FOR FURTHER INFORMATION CONTACT: The FinCEN regulatory helpline at (800) 949-2732.

SUPPLEMENTARY INFORMATION:

I. Background

On April 14, 2010, FinCEN published a final rule¹ to include mutual funds within the general definition of “financial institution” in regulations implementing the BSA (the “Final Rule”).² The Final Rule subjects mutual funds to rules under the BSA on the filing of Currency Transaction Reports (“CTRs”) and on the creation, retention,

and transmittal of records or information for transmittals of funds. Additionally, the Final Rule amends the definition of mutual fund in the rule requiring mutual funds to establish anti-money laundering (“AML”) programs. The amendment harmonizes the definition of mutual fund in the AML program rule with the definitions found in the other BSA rules to which mutual funds are subject. Finally, the Final Rule amends the rule that delegates authority to examine institutions for compliance with the BSA. The amendment makes it clear that FinCEN has not delegated to the Internal Revenue Service the authority to examine mutual funds for compliance with the BSA, but rather to the U.S. Securities and Exchange Commission as the Federal functional regulator of mutual funds.

Section 103.33—The Recordkeeping and Travel Rule and Related Recordkeeping Requirements

The Final Rule subjects mutual funds to requirements relating to the creation and retention of records for transmittals of funds, and the requirement to transmit information on these transactions to other financial institutions in the payment chain (“Recordkeeping and Travel Rule”).³ The Recordkeeping and Travel Rule applies to transmittals of funds in amounts that equal or exceed \$3,000,⁴ and requires the transmitter’s financial institution to obtain and retain name, address, and other information on the transmitter and the transaction.⁵ Furthermore, the Recordkeeping and Travel Rule requires the recipient’s financial institution—and in certain instances, the transmitter’s financial institution—to obtain or retain identifying information on the recipient.⁶ The Recordkeeping and Travel Rule requires that certain information obtained or retained by the transmitter’s financial institution

“travel” with the transmittal order through the payment chain.⁷

Mutual funds are subject to record retention requirements under the Investment Company Act of 1940, and mutual fund transfer agents are subject to recordkeeping requirements under the Securities Exchange Act of 1934.⁸ In light of these existing regulatory obligations, FinCEN stated in the notice of proposed rulemaking that the requirements of 31 CFR 103.33 and 31 CFR 103.38 would have a *de minimus* impact on mutual funds and their transfer agents.⁹ Furthermore, rules under the BSA on the establishment of customer identification programs by mutual funds and on the reporting by mutual funds of suspicious transactions impose requirements to create and retain records.¹⁰

FinCEN also requested comment on the anticipated impact of subjecting mutual funds to the requirements of the Recordkeeping and Travel Rule. All three commenters noted that subjecting mutual funds to the requirements of the Recordkeeping and Travel Rule will require mutual funds to implement changes to their transaction processing and recordkeeping systems. All commenters requested additional time to comply with the Recordkeeping and Travel Rule. Commenters stated that such an extension would provide mutual funds with an opportunity to implement changes to their transaction reporting and recordkeeping systems. Generally, commenters suggested an extension of between 18 to 24 months. FinCEN determined that extending the compliance date with respect to the requirements of the Recordkeeping and Travel Rule to 270 days after the rule

⁷ See 31 CFR 103.33(g) (information that must “travel” with the transmittal order); 31 CFR 103.11(kk) (defining “transmittal order”). Additionally, the Final Rule includes mutual funds within an existing exception designed to exclude from the Recordkeeping and Travel Rule’s coverage funds transfers or transmittal of funds in which certain categories of financial institution are the transmitter, originator, recipient, or beneficiary. See 31 CFR 103.33(e)(6)(i) and 31 CFR 103.33(f)(6)(i). Further, the Final Rule subjects mutual funds to requirements on the creation and retention of records for extensions of credit and cross-border transfers of currency, monetary instruments, checks, investment securities, and credit. See 31 CFR 103.33(a)–(c). Financial institutions must retain these records for a period of five years. 31 CFR 103.38(d).

⁸ See, e.g., 15 U.S.C. 80a–30 (mutual funds); 15 U.S.C. 78q(a)(3) (transfer agents).

⁹ Amendment to Bank Secrecy Act Regulations; Defining Mutual Funds as Financial Institutions, 74 FR 26996, 26998 (June 5, 2009).

¹⁰ See 31 CFR 103.131 (mutual funds must obtain and record identifying information for persons opening new accounts, and verify the identity of persons opening new accounts); 31 CFR 103.15(c) (mutual funds must maintain records of documentation that supports the filing of a SAR).

¹ Amendments to the Bank Secrecy Act Regulations; Defining Mutual Funds as Financial Institutions, 75 FR 19241 (April 14, 2010).

² See 31 CFR 103.11(n)(10) (general definition of “financial institution”). The BSA is codified in part at 31 U.S.C. 5311 *et seq.* Rules implementing the BSA are codified at 31 CFR part 103.

³ See 31 CFR 103.33(f) and (g). Financial institutions must retain records for a period of five years. 31 CFR 103.38(d).

⁴ Rules under the BSA define a “transmittal of funds” and the persons or institutions involved in a “transmittal of funds.” See 31 CFR 103.11(d), (e), (q), (r), (s), (v), (w), (cc), (dd), (jj), (kk), (ll), and (mm). A “transmittal of funds” includes funds transfers processed by banks, as well as similar payments where one or more of the financial institutions processing the payment is not a bank. If the mutual fund is processing a payment sent by or to its customer, then the mutual fund would be either the “transmitter’s financial institution” or the “recipient’s financial institution.”

⁵ See 31 CFR 103.33(f)(1)(i) and (f)(2).

⁶ See 31 CFR 103.33(f)(3) (information that the recipient’s financial institution must obtain or retain).

was published in the **Federal Register** (January 10, 2011) was appropriate.

On July 13, 2010, the Investment Company Institute (“ICI”) ¹¹ submitted a letter stating that it will be difficult for its members to comply with the Recordkeeping and Travel Rule by January 10, 2011. Due to unique industry end-of-year systems issues,¹² as well as systems changes necessitated by other new regulatory requirements,¹³ the ICI has requested a three month extension of the date by which mutual funds are required to comply with the requirements of the Recordkeeping and Travel Rule.

II. Extension of Compliance Date for the Recordkeeping and Travel Rule

FinCEN believes that it is appropriate to extend the date by which mutual funds must comply with the Recordkeeping and Travel Rule. Therefore, mutual funds now will have until April 10, 2011 to comply with 31 CFR 103.33. We do not anticipate granting a further extension beyond April 10, 2011 and expect that mutual funds thereafter will have adequate processes in place to comply with the Recordkeeping and Travel Rule.

¹¹ The ICI is an association of U.S. investment companies, including mutual funds, closed-end funds, exchange-traded funds (ETFs), and unit investment trusts (UITs). Members of ICI manage total assets of \$11.42 trillion and serve 90 million shareholders.

¹² According to the ICI, most mutual funds and transfer agents refrain from implementing material modifications or enhancements to their transaction processing and recordkeeping systems for varying periods beginning in early December (generally referred to as a “freeze”) to ensure that the systems are capable of handling the large number of end-of-year fund and shareholder transactions, as well as the preparation of year-end account statements and tax reporting information. Because the January 10, 2011 compliance date falls within the period when mutual fund transaction processing and recordkeeping systems are frozen, mutual funds will need to come into compliance with the Recordkeeping and Travel Rule by the middle of November 2010—before the systems are frozen. A three-month extension of the compliance date would allow mutual funds sufficient time to come into compliance with the Recordkeeping and Travel Rule without disrupting the year-end operations and reporting functions.

¹³ According to the ICI, mutual fund transfer agents are currently redesigning their systems in order to comply with new cost basis reporting requirements, which entail significant operational and technological changes to allow funds to capture, report, and transfer required tax information, such as when shareholders transfer their accounts (see Basis Reporting by Securities Brokers and Basis Determination for Stock, 74 FR 67010 (Dec. 17, 2009)). In addition, mutual funds and their transfer agents are updating their systems to comply with a new requirement that money market mutual funds and their transfer agents be able to process purchases and redemptions electronically at a price other than \$1.00 per share (see Money Market Fund Reform, SEC Release No. IC-29132 (Jan. 27, 2010)).

III. Proposed Location in Chapter X

As discussed in a previous **Federal Register** Notice, 73 FR 66414, Nov. 7, 2008, FinCEN is separately proposing to remove Part 103 of Chapter I of Title 31, Code of Federal Regulations, and add Parts 1000 to 1099 (Chapter X). If the notice of proposed rulemaking for Chapter X is finalized, the changes in the present rule would be reorganized according to the proposed Chapter X. The planned reorganization will have no substantive effect on the regulatory changes herein. The regulatory changes of this specific rulemaking would be renumbered according to the proposed Chapter X as follows: § 103.33 would be moved to § 1010.410.

IV. Notice and Comment Under the Administrative Procedure Act

FinCEN for good cause finds that, for the reasons cited above, including the brief length of the extension we are granting, notice and solicitation of comment regarding the extension of the compliance date are impracticable, unnecessary and contrary to the public interest. In this regard, FinCEN notes that mutual funds need to be informed as soon as possible of the extension and its length in order to plan and adjust their implementation processes accordingly.¹⁴

Dated: October 6, 2010.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2010-25886 Filed 10-14-10; 8:45 am]

BILLING CODE 4810-02-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2008-HA-0029]

RIN 0720-AB45

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals

AGENCY: Office of the Secretary, Department of Defense (DoD).

¹⁴ See 5 U.S.C. 553(b)(3)(B) (an agency may dispense without prior notice and comment when it finds, for good cause, that notice and comment are “impracticable, unnecessary, and contrary to the public interest”). The change to the compliance date is effective upon publication in the **Federal Register**. The Administrative Procedure Act allows effective dates less than 30 days after publication in the **Federal Register** for “a substantive rule which grants or recognizes an exemption or relieves a restriction.” See 5 U.S.C. 553(d)(1).

ACTION: Final rule.

SUMMARY: Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA-08) states with respect to any prescription filled on or after the date of enactment, the TRICARE Retail Pharmacy Program shall be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.), to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by network retail pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in such section 8126. DoD issued a final rule on March 17, 2009, implementing the law. On November 30, 2009, the U.S. District Court for the District of Columbia remanded the final rule to DoD (without vacating the rule) for DoD to consider in its discretion whether to readopt the current iteration of the rule or adopt another approach. This final rule is the product of that reconsideration. DoD is readopting the 2009 final rule, with some revision.

DATES: This final rule is effective December 27, 2010.

FOR FURTHER INFORMATION CONTACT: Rear Admiral Thomas McGinnis, Chief, Pharmacy Operations Directorate, TRICARE Management Activity, telephone 703-681-2890.

SUPPLEMENTARY INFORMATION:

A. Background

Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA-08) (Pub. L. 110-181) enacted 10 U.S.C. 1074g(f). It provides that with respect to any prescription filled on or after the date of enactment (January 28, 2008), the TRICARE Retail Pharmacy Program shall be treated as an element of DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. 8126 to the extent necessary to ensure pharmaceuticals paid for by DoD that are provided by network retail pharmacies to TRICARE beneficiaries are subject to Federal Ceiling Prices (FCPs). This section 8126 established FCPs for covered drugs (requiring a minimum 24% discount) procured by DoD and three other agencies from manufacturers. The NDAA required implementing regulations.

DoD issued a proposed rule July 25, 2008 (73 FR 43394-97) and a final rule March 17, 2009 (74 FR 11279-93). Among other things, the preamble to the final rule stated that DoD interpreted the statute as automatically capping the price manufacturers may get paid for

those covered drugs that enter into the commercial chain of transactions that end up as TRICARE-paid retail prescriptions, resulting in the conclusion that the amount above the FCP was an overpayment by DoD, which in turn required a refund of the overpayment. Ruling on a litigation challenge to the final rule in a case called *Coalition for Common Sense in Government Procurement v. U.S.*, the U.S. District Court for the District of Columbia decided on November 30, 2009, that although 10 U.S.C. 1074g(f) requires that FCPs shall apply, the statute does not specify *how* they will apply. The Court ruled that DoD incorrectly interpreted the statute as requiring manufacturer refunds, to the exclusion of other possible approaches, and ordered DoD to reconsider the implementation of the statute as a function of its discretionary judgment, rather than only as a legal interpretation. The Court also ruled that

while DoD considers whether to readopt the final rule as it currently stands or to change it, the final rule and the manufacturer agreements will remain in effect. Finally, the Court held that DoD correctly interpreted the statute as applying Federal Ceiling Prices to all prescriptions filled on or after January 28, 2008.

To help DoD carry out the reconsideration ordered by the Court, on February 8, 2010, DoD published a notice in the **Federal Register** inviting additional public comments on the 2009 final rule, as well as additional comments regarding any other appropriate and legally permissible implementation approach. DoD recommended that interested parties focus their comments on those matters addressed by the Court. The Notice further advised that in considering alternative approaches to implementing the statute, DoD intended to use at least the following three criteria (and

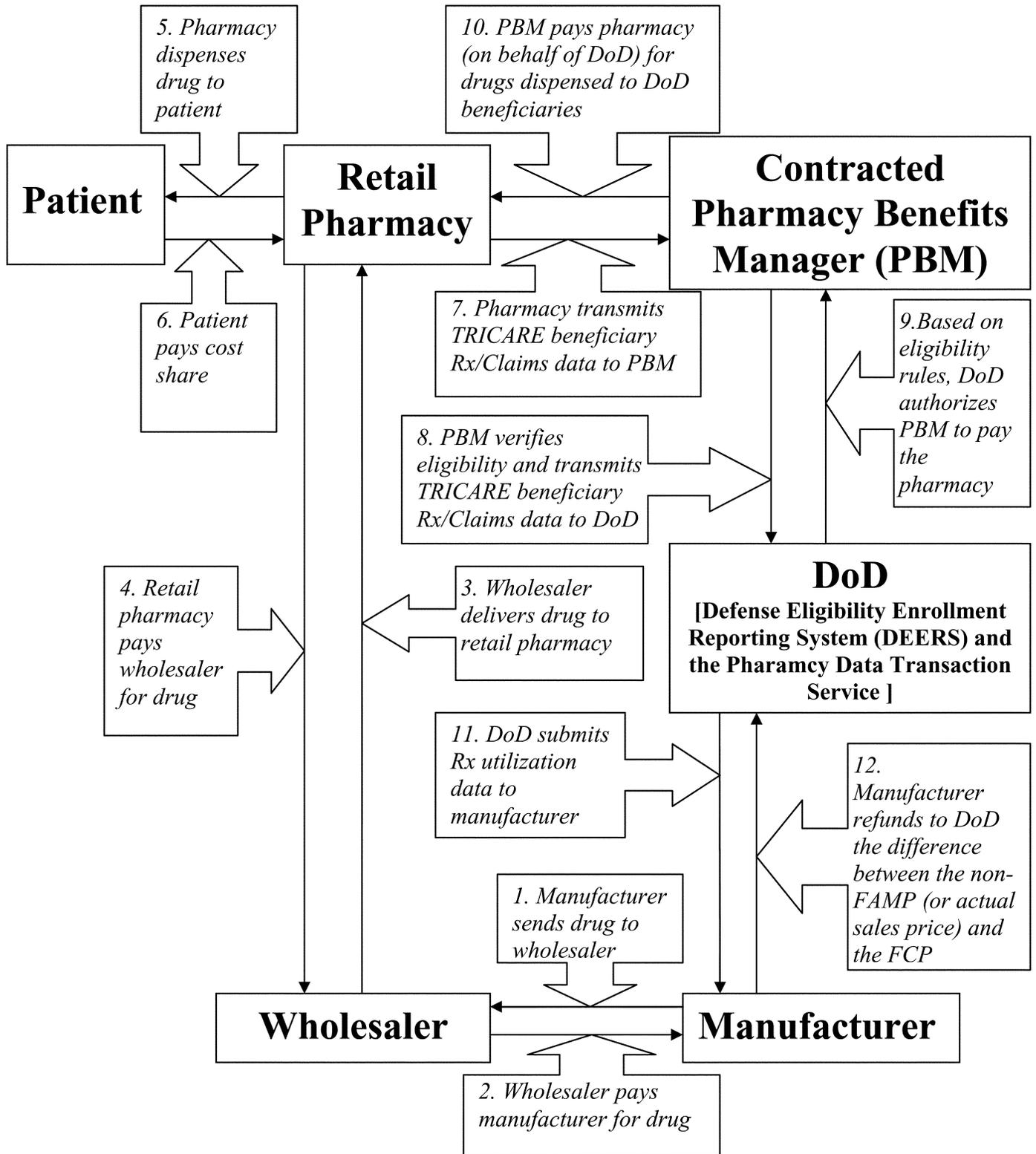
welcomed comment on these and other suggested criteria): (1) Harmony with the statute and legislative history; (2) consistency with best business practice; and (3) practicability of administration.

DoD received eleven public comments. Five were from representatives of the pharmaceutical manufacturing industry, two from representatives of the retail pharmacy industry, two from specialty providers participating in the Department of Health and Human Services' 340B program, one from a representative of pharmaceutical wholesalers, and one from a pharmacy benefits manager.

Before discussing the major issues for reconsideration and the public comments received, Figure 1 is provided to assist in understanding the operation of the TRICARE Retail Pharmacy Program as it currently operates.

BILLING CODE 5001-06-P

Figure 1: Steps in TRICARE Retail Pharmacy Program Transactions



B. Major Issues for Reconsideration

There are four major issues for reconsideration: (1) *Who* bears the burden of applying FCPs? (2) *How* will FCPs be applied? (3) *When* do FCPs apply? (4) *To what* do FCPs apply? The first two of these issues are the ones that the Court specifically ordered DoD to reconsider as a matter of DoD's discretionary judgment. The last two were not covered by that specific Court order to DoD but were addressed by the Court and by commenters. These four major issues will be addressed in turn.

1. Who bears the burden of applying FCPs?

The Court framed this issue, stating that DoD should exercise its discretion to consider "which of the five parties that participate in the retail pharmacy program—manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries—must bear any costs associated with imposing the Federal Ceiling Prices."

For purposes of this regulation, DoD has considered the five options identified by the Court (DoD recognizes that a comprehensive analysis of distributional effects would involve a detailed market analysis). Representatives of retail pharmacies, wholesalers, and pharmacy benefits managers argued strongly that FCPs are *manufacturer* ceiling prices under 38 U.S.C. 8126 and that the economic burden necessarily falls on manufacturers. Pharmaceutical industry representatives that submitted comments did not contest this point, propose any of the four alternative options, or otherwise comment on this issue.

(a) *Assessment of options for harmony with the statute and legislative history concerning who bears the burden of FCPs.*

Section 1074g(f) provides that "the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense * * * are subject to the pricing standards in such section 8126." Section 8126 provides that "[e]ach manufacturer of covered drugs shall enter into a master agreement with the Secretary under which * * * with respect to each covered drug of the manufacturer procured by [DoD and certain other agencies] that is purchased under depot contracting systems or listed on the Federal Supply Schedule,

the manufacturer has entered into and has in effect a pharmaceutical pricing agreement with the Secretary" of Veterans Affairs "under which the price charged * * * may not exceed 76 percent of the non-Federal average manufacturer price [non-FAMP]. * * *" Section 8126 goes on to define "manufacturer" as excluding "a wholesale distributor of drugs or a retail pharmacy."

Taken together, the texts of the two statutes support the view that Federal Ceiling Prices refer to manufacturer prices, not to wholesalers' prices or retail pharmacies' prices; that FCPs are the ceiling prices that manufacturers may charge or be paid by the covered Federal agencies, which may not exceed 76 percent of the average manufacturer price applicable to non-Federal purchasers; that these maximum manufacturer prices apply to covered drugs procured by the agencies, including DoD; and that the TRICARE Retail Pharmacy Program shall be treated as part of DoD for purposes of this procurement to the extent necessary to ensure that these maximum manufacturer prices apply to covered drugs paid for by DoD through this Program.

The other two participants in the TRICARE Retail Pharmacy Program are the pharmacy benefits manager, which is a company that functions essentially as a management agent for DoD, and the beneficiary. The pharmacy benefits manager is not mentioned in section 1074g or section 8126. The financial responsibility of TRICARE beneficiaries under the Pharmacy Benefits Program is specifically addressed in section 1074g(a)(6), which provides explicit maximums on beneficiary costs.

Based on these statutory provisions, the option that manufacturers bear the burden of FCPs is in harmony with the statutes, which establish FCPs as a ceiling on manufacturer prices. The option that retail pharmacies bear the burden is not in harmony because section 8126 specifically excludes retail pharmacies from the definition of manufacturer for purposes of identifying entities covered by FCPs. The same is true of the option that wholesalers bear the burden of FCPs. The option that beneficiaries bear the burden of FCPs is not in harmony with section 1074g, which separately specifically establishes maximum limits on beneficiary costs. The option that pharmacy benefits managers bear the burden of FCPs is not addressed by the statutory texts.

In addition to the statutory texts, the legislative history of section 1074g(f) is noteworthy. As previously addressed, section 1074g(f) was enacted as part of

NDAA-08. A very similar provision was included in the Senate-passed version of the proposed National Defense Authorization Act for Fiscal Year 2007 (NDAA-07), but was not enacted in the final version. That provision, like the NDAA-08 provision eventually enacted, said the TRICARE Retail Pharmacy Network "shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38." The Senate Armed Services Committee explained that the purpose of the provision was to "affirm a decision made by the Secretary of Veterans Affairs * * * that drugs purchased by the TRICARE retail pharmacy network are subject to the same federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program." (S. Rept. 109-254, 109th Cong. 2d Sess., May 9, 2006, pp. 342-343.) The Secretary of Veterans Affairs decision that the Senate proposed to affirm through language quite similar to that eventually enacted placed the burden of FCPs on manufacturers, not on retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries. Similarly, the federal pricing limits that have long applied to military facility pharmacies and the mail order program, which the Senate proposal sought also to apply to drugs provided through the retail network, place the financial burden on manufacturers, not on any other participants in those transactions, such as the pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries.

The legislative history of 38 U.S.C. 8126 is also notable. That section was enacted by section 603 of the Veterans Health Care Act of 1992. The Senate Committee Report described the provision as one intended to ensure "reasonable prices" from manufacturers and explained that the 24 percent discount from non-FAMP was based on "the Congressional Budget Office's estimate of the median percentage discount received" through the Medicaid manufacturer rebate program, which in turn is based on the "best price" manufacturers charge customers. (S. Rept. No. 102-401, 102d Cong., 2d Sess., September 15, 1992, pp. 68-70, reprinted in 1992 U.S. Code Congressional and Administrative News, pp. 4158-60.)

Therefore, the option of manufacturers bearing the financial burden of FCPs under section 1074g(f) is in harmony with the legislative history of both 10 U.S.C. 1074g(f) and 38

U.S.C. 8126. None of the other options is in harmony with the legislative history. Further, there is no legislative history hinting that the financial burden of FCPs, which § 8126 places on manufacturers, was intended by § 1074g(f) to be shifted to retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries, or that § 1074g(f) was intended to regulate the financial activities of retail pharmacies, wholesalers, pharmacy benefits managers, or beneficiaries.

(b) *Assessment of options for consistency with best business practice concerning who bears the burden of FCPs.*

Assuming that the only requirement of the statute applies to the amount paid by DoD in the retail pharmacy program and that DoD can implement that requirement by allocating financial burden on any of the five identified participants, the issue here is to assess what allocation is consistent with best business practice. As a matter of business management, the TRICARE Pharmacy Benefits Program provides outpatient pharmaceuticals through three venues: Military facility pharmacies, the mail order pharmacy, and retail pharmacies. All three venues involve four categories of costs: Manufacturing costs, distribution costs, management costs, and prescription filling costs; and all three have potential cost sharing with beneficiaries. In military facility pharmacies, manufacturing costs for covered drugs are subject to FCPs under 38 U.S.C. 8126, and potentially larger discounts through competitive market procedures. Distribution costs are paid to wholesalers under prime vendor contracts based on competitive processes. Management costs are incurred through direct costs of the Defense Logistics Agency, a component of the Department of Defense. Prescription filling costs are incurred through direct costs of military and civilian personnel, expenses, and operations of outpatient pharmacies in military hospitals and clinics. Cost sharing by beneficiaries is subject to some policy discretion by DoD; there are no beneficiary co-payments for outpatient services in military facilities.

In the mail order pharmacy program, as in military facility pharmacies, manufacturing costs for covered drugs are subject to FCPs under 38 U.S.C. 8126, and potentially larger discounts through competitive market procedures. Distribution costs are paid by DoD to wholesalers under prime vendor contracts. Management and prescription filling costs are incurred by the mail order pharmacy program contractor and

paid by DoD based on prices set in the competitive contracting process. Cost sharing by beneficiaries is set by DoD regulation, subject to specifications in 10 U.S.C. 1074g and based on a policy structure aimed at encouraging use of the mail order venue and more cost-effective drugs.

The retail pharmacy system in the United States is part of the American health care system, of which the DoD health system is a relatively small part. In the normal commercial chain, manufacturers sell their pharmaceuticals to wholesalers. Wholesalers add to the manufacturing costs (*i.e.*, the costs incurred in purchasing the drugs from the manufacturers) an amount that covers distribution expenses and profit (possibly including in these calculations prompt payment discounts or other incentives) and charge this price to retail pharmacies. Retail pharmacies take the manufacturing costs and the distribution costs and add an amount to cover the retail pharmacies' expenses in salaries and operations and a profit (possibly factoring in incentives in exchange for network agreements with pharmacy benefit managers), and arrive at a price reflecting manufacturing, distribution, and prescription costs. This amount is typically billed to a pharmacy benefits manager, functioning as an administrative agent for a health plan sponsor, after collecting a limited portion of the amount as the beneficiary's co-payment. The plan sponsor ultimately pays the roll-up of the manufacturing, distribution, prescription, and management costs.

In this system, prevailing business practice for a plan sponsor is to get the best value that is feasible at each step of the commercial chain. The plan sponsor negotiates and contracts directly with the pharmacy benefits manager, seeking the best value in the management costs incurred in return for the success of the pharmacy benefits manager in meeting overall plan objectives for beneficiary services and cost-effectiveness. The plan sponsor also sets beneficiary co-payment amounts based on applicable dynamics that may include collective bargain agreements, employer policy, and the like, as well as management objectives in influencing market share toward more cost-effective drugs and points of service. Either the plan sponsor or the pharmacy benefits manager will seek best value regarding manufacturing costs, distribution costs, and prescription costs through whatever tools are feasible in dealing with manufacturers, wholesalers, and retail pharmacies respectively.

In this system, best business practice for the TRICARE Pharmacy Benefits Program is to seek to achieve best value with respect to each of the four categories of cost and with respect to the matter of beneficiary cost sharing. For purposes of this assessment of retail program options, the assumption is that the final cost to DoD must somehow reflect the implementation of FCPs somewhere in the system, whether in relation to manufacturing costs, distribution costs, prescription costs, management costs, or beneficiary cost sharing, or some combination of these. The most obvious option is to apply FCPs to manufacturing costs in the retail program because FCPs apply to manufacturing costs in the military facility and the mail order components of the program. Alternatively, DoD could permit higher manufacturing costs for the retail program than are legal in the military facility or mail order programs, and somehow offset that higher cost by lowering distribution, prescriptions, or management costs or increasing beneficiary co-payments. Neither DoD nor DoD's pharmacy benefits manager has much practical ability to have wholesalers pass on to retail pharmacies less than their normal amounts in order to offset DoD's ultimate manufacturing costs that exceed the FCPs.

Although drug manufacturers argue that retail pharmacies enjoy a mark-up over what they pay wholesalers, the DoD's pharmacy benefits manager already negotiates network agreements with retail pharmacies that seek best value, consistent with DoD policy objectives on maintaining a very large retail pharmacy network, currently more than 60,000 pharmacies. In theory, DoD could limit payments to retail pharmacies so as to offset the absence of the FCP 24% discount in manufacturing costs, but the predictable effect of this would be that most or all retail pharmacies would drop out of the network, resulting in an inability of DoD to extend the benefits of the network system to many military families. DoD policy favors a very large pharmacy network because military families, which include spouses and children of deployed military members and also include Reserve Component families, are in communities all over the United States. Retail pharmacy industry commenters stated they had no economic ability to absorb such reductions, and that is consistent with DoD's understanding.

The other two participants in the retail pharmacy enterprise are the pharmacy benefits manager and the beneficiary. With respect to the

pharmacy benefits manager, DoD's management costs are the product of the competitive selection of a pharmacy benefits manager contractor under the Competition in Contracting Act. Manufacturing costs are pass-through costs under this contract, so there is no opportunity for the pharmacy benefits manager contractor to absorb the higher manufacturing costs that would result from not applying FCPs to manufacturing costs. Finally, beneficiary co-payments are the means to encourage beneficiaries to favor more cost-effective drugs and service venues, and must conform to a set of statutory specifications. There is little or no room to accommodate these requirements and objectives and also to offset the absence of a 24% discount in manufacturing costs.

A recent Congressional Budget Office report, "Prescription Drug Pricing in the Private Sector," January 2007, used available private sector economic data to construct a hypothetical example of payments for a single-source prescription. In this example, the plan sponsor paid a total of \$88 for a prescription, of which \$74 went to the manufacturer (manufacturing cost), \$3 to the wholesaler (distribution cost), \$5 to the retail pharmacy (prescription fill cost), and \$6 to the pharmacy benefits manager (management cost). The economics reflected in the relative amounts in this example support the view that best business practice is to treat FCPs as applicable to manufacturing costs, and therefore the manufacturer prices. Further, pharmaceutical industry representatives have never asserted that they do not make a profit at the Federal Ceiling Price or that the economics could support assessing the burden of FCPs on any other participant.

Based on all of these factors, best business practice is for DoD to deal with management costs through the best value competitive selection of a pharmacy benefits manager; prescription fill costs through the pharmacy benefits manager's network pharmacy negotiations, consistent with overall health program objectives; beneficiary co-payments based on incentives for cost-effective utilization, consistent with statutory specifications; distribution costs, to the extent there is any feasibility, indirectly through retail network negotiations; and manufacturing costs by applying FCPs in a manner comparable to the application of FCPs to manufacturing costs in the military facility and mail order programs. Therefore, based on the criteria of best business practice, DoD has concluded that the financial burden

of FCPs is properly assigned to drug manufacturers.

(c) Assessment of options for practicability of administration concerning who bears the burden of FCPs.

Again assuming that the only requirement of the statute applies to the amount paid by DoD in the retail pharmacy program and that DoD can implement that requirement by allocating financial burden on any of the five identified participants, the issue here is to assess what allocation is consistent with practicability of administration. The allocation of the financial burden of FCPs to manufacturers in the context of a retail pharmacy program can be administered through a rebate/refund apparatus, possibly among other options (which will be discussed below). A rebate system is common practice in the industry and was used by the TRICARE Retail Pharmacy Program prior to the enactment of NDAA-08 to implement a program of formulary-based manufacturer discounts.

Allocating the financial burden to wholesalers is not practicable because, like most plan sponsors, DoD has no relationship with wholesalers in the distribution mechanisms of the retail pharmacy system in the United States. Further, as pointed out by a commenter, it is not clear how DoD could identify from prescription claims data the identity of the wholesaler that sold the drugs to the retail pharmacy since there is nothing comparable to a National Drug Code (NDC) number, which identifies the manufacturer. An administrative system for imposing FCPs on retail pharmacies could presumably be created that would limit payments to FCPs plus a reasonable prescription filling fee, but this would not avoid the retail pharmacy losing money on each transaction. Under the current pharmacy benefit manager relationship, there is no practicable way to allocate the financial burden of FCPs to the TRICARE pharmacy benefits manager because manufacturing costs are a pass-through to DoD and there is no basis to subtract an amount equal to 24% of total manufacturing costs from the management fee DoD pays the pharmacy benefits manager, that total fee being a far lesser amount. An administrative system for allocating the financial burden of FCPs to beneficiaries in the form of co-payments increased by an amount equal to 24% of manufacturing costs would be feasible to design but not to implement because it would far exceed the maximum co-payment amounts allowed by 10 U.S.C. § 1074g. Thus, all things considered,

DoD has concluded that allocating the financial burden of FCPs to manufacturers is the most practicable of administration.

(d) Conclusion on who bears the burden of applying FCPs.

Considering harmony with the statute and legislative history, best business practice, and practicability of administration, DoD has concluded that it is most appropriate that manufacturers bear the burden of applying FCPs to the TRICARE Retail Pharmacy Program. No commenter contested this conclusion or proposed a different option.

2. How are FCPs applied?

Accepting that for the reasons discussed above FCPs apply to manufacturer prices, the second issue is how FCPs will be applied to manufacturer prices. In the proposed and final rules, DoD applied FCPs to manufacturer prices through manufacturer refunds to DoD of amounts received by the manufacturers for covered prescriptions paid for by the TRICARE Retail Pharmacy Program. The Court's opinion of November 30, 2009, stated that "Congress did not speak to the 'precise question' of how the Department should implement the statute's requirements." The opinion continued:

Indeed, the Court can imagine several other regulatory schemes consistent with 10 U.S.C. 1074g(f) that the Department could have chosen. For example, instead of requiring pharmaceutical manufacturers to pay DoD the amounts in excess of the Federal Ceiling Prices, a rule could require manufacturers to reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. Or DoD arguably could have adjusted the retail pharmacy mark-ups or dispensing fees to ensure that the Department did not pay more than Federal Ceiling Prices. The Coalition suggests two additional possibilities: "DoD could have contracted with pharmacies to purchase TRICARE beneficiaries' drugs * * * at the Federal Ceiling Price," or "DoD could have procured drugs directly from manufacturers at the Federal Ceiling Price and then distributed the drugs to pharmacies."

The manufacturer refund method as well as the four alternative options noted in the Court's opinion have been considered. DoD also considered two other options that are used in other parts of the TRICARE Pharmacy Benefits Program—vendor charge-backs and replacement inventories. No other options on how to apply FCPs to

manufacturer prices were presented by commenters, including commenters representing pharmaceutical manufacturers, and no commenters recommended a method other than manufacturer rebates or refunds.

(a) *Assessment of options for harmony with the statute and legislative history concerning how FCPs are applied.*

10 U.S.C. 1074g(f) provides that “with respect to any prescription filled * * *, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense * * * are subject to the pricing standards in such section 8126.”

The manufacturer refund method of implementation is in harmony with the statute. In the case of Department of Defense procurement of drugs under § 8126, the drug manufacturer’s price may not exceed the FCP and the manufacturer is not paid more than the FCP. Under § 1074g(f), a prescription filled in the TRICARE retail pharmacy program and paid for by DoD should produce the same outcome. The manufacturer refund method produces the same outcome because the manufacturer refunds to DoD the amount above the FCP that the manufacturer had been paid when the manufacturer began the chain of transactions that ended with the prescription being filled through the TRICARE retail pharmacy program. Thus, DoD’s net manufacturing cost is at the FCP and the manufacturer’s net price is at the FCP.

The first alternative option is that instead of requiring pharmaceutical manufacturers to refund to DoD the amounts in excess of the Federal Ceiling Prices, a rule could require manufacturers to reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. If a practicable way could be devised to identify prospectively the subset of drugs that will end up as TRICARE retail pharmacy program prescriptions out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler, this alternative could also be in harmony with the statute.

The second alternative option is that DoD could perhaps adjust the retail pharmacy mark-ups or dispensing fees to ensure that the Department did not pay more than Federal Ceiling Prices. If this occurs after the manufacturer has already been paid more than the FCP by

the wholesaler (e.g., been paid at the average manufacturer price) and the wholesaler passed that higher price on to the retail pharmacy, harmony with the statute and the resolution of issue number one (on who bears the burden of FCPs) would require some further transaction between the retail pharmacy and the manufacturer (such as a manufacturer rebate/refund to the retail pharmacy) so that the FCP pricing standard actually applies to the manufacturer. Were this accomplished, then the manufacturing cost portion of the amount the retail pharmacy charges DoD could be held down to the FCP, and the result would be in harmony with the statute.

The third alternative option is that DoD could contract with pharmacies to allow those pharmacies to purchase drugs for distribution to TRICARE beneficiaries at the Federal Ceiling Price. Were a practicable method devised for this approach, it would be in harmony with the statute because prescriptions filled in the TRICARE retail pharmacy program would be with drugs for which manufacturers were paid at the FCPs and the savings would be passed on the DoD through the arrangement between DoD and the retail pharmacies.

The fourth alternative option would be for DoD to procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies. Were a practicable method devised for this approach, it would also be in harmony with the statute because prescriptions filled in the TRICARE retail pharmacy program would be with drugs for which manufacturers were paid directly by DoD at the FCP.

The fifth alternative option is the vendor charge-back method, under which the wholesaler obtains a refund from the manufacturer for pharmaceuticals that the wholesaler passes down stream to retail pharmacies for TRICARE beneficiaries. This system is used in the military system for drugs sold by wholesalers to military facility pharmacies, the charge-back to the manufacturer being based on FCPs or lower contracted prices. Were a feasible method devised for managing the retail transactions for exclusive use for TRICARE beneficiaries, this approach would be in harmony with the statute.

The sixth alternative option is the replacement inventory approach, under which the pharmacy fills TRICARE prescriptions from its regular inventory of drugs, but is allowed to replace this inventory from DoD’s prime vendor wholesaler, which then uses the vendor charge-back to the manufacturer. This

system is used for the TRICARE Mail Order Program contractor. Were a feasible method developed for managing the transactions throughout the retail pharmacy network to limit replacement inventory to actual TRICARE prescriptions filled, this approach would be in harmony with the statute.

Thus, the manufacturer refund method is in harmony with the statute, as are the last four alternative options if they could be feasibly implemented. The other two alternatives, with sufficient other conditions met, could also be in harmony.

(b) *Assessment of options for consistency with best business practice concerning how FCPs are applied.*

The mechanism of manufacturer refunds is the established industry practice in the retail pharmacy system in the United States for manufacturers to provide price discounts—i.e., reductions below the average manufacturer price applicable to sales to wholesalers—to health plan sponsors. No commenter contested this point. The manufacturer refund method of implementation is consistent with best business practice.

The first alternative option is that instead of requiring pharmaceutical manufacturers to refund or rebate to DoD the amounts in excess of the Federal Ceiling Prices, manufacturers could reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. This option does not fit normal industry practice, which cannot identify the subset of drugs that will end up as prescriptions paid for by a particular health plan sponsor out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler. No commenter recommended this alternative option.

The second alternative option—that the plan sponsor reduce payments to retail pharmacies by an amount corresponding to a manufacturing cost discount of 24% below the non-Federal average manufacturer price, expecting other arrangements among retail pharmacies, wholesalers, and manufacturers to accommodate those participants’ commercial viability—is also outside the realm of established business practice in the retail pharmacy system in the United States. No commenter recommended this alternative option.

The third alternative option is that pharmacies purchase drugs from manufacturers earmarked for particular health plan beneficiaries so as to achieve different ultimate health plan costs for different health plans,

depending on the degree of discount the manufacturer intends for the particular plan sponsor. With so many different plan sponsors and so many thousands of retail pharmacies, this is not a system that is in use in the industry. No commenter recommended such a system for implementing FCPs for the TRICARE Retail Pharmacy Program.

The fourth alternative option—that the plan sponsor procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies for use in filling prescriptions to beneficiaries of the plan sponsor—is not an established system in the retail prescription drug system in the United States. It would require multiple product distribution and vast inventory management systems wholly different from those currently in use. No commenter recommended such a system.

The fifth alternative option, the vendor charge-back by the wholesaler to the manufacturer, is not a prevailing method for very large retail networks. It is in use in restricted pharmacy systems, like military facility pharmacies, where all beneficiaries are eligible for prescriptions filled with the drugs covered by the discounted price so that the vendor charge back can be applied to all drugs moving from the wholesaler to the retailer. In the large, non-restricted retail pharmacy network context, only a relatively small fraction of prescription drug customers of those pharmacies are TRICARE beneficiaries and only this fraction of prescriptions is covered by the discounted price. In such a context, a business process between manufacturers and wholesalers does not accommodate the manufacturer's desire to restrict the discount to a small subset of eventual retail customers.

The sixth alternative option, the replacement inventory approach, is also not a prevailing method for very large retail networks because of a need to track and audit the retail transactions to prevent diversion of discounted drugs to customers not eligible for the discounts. DoD uses this method with its mail order contractor, which is a single pharmacy, rather than a network of more than 60,000 pharmacies.

Thus, the manufacturer refund method is most consistent with established business practice in the retail prescription drug pharmacy system in the United States, and no commenter recommended an approach other than manufacturer rebates or refunds to apply FCPs to the TRICARE Retail Pharmacy Program.

(c) Assessment of options for practicability of administration concerning how FCPs are applied.

The manufacturer refund method of implementation is practicable administratively. Before the enactment of NDAA–08, the TRICARE Retail Pharmacy Program implemented a system of Voluntary Agreements for Retail Rebates (VARRs), which utilized the same apparatus as the refund program under the 2009 final rule. That apparatus includes an accounting through the data systems of prescriptions provided to TRICARE beneficiaries, submission of these data to manufacturers on a quarterly basis, procedures to reconcile any differences or disagreements between the manufacturer's data and DoD's data, and rebate/refund payments by the manufacturer to DoD of the amount in excess of the target price. Under the VARRs system the target price was that established in the agreement, which could be above or below the FCP. Under the final rule, the target price may be no higher than the FCP, but may be lower. The administrative apparatus, however, is the same. It is well established and works effectively.

The first alternative option is that instead of pharmaceutical manufacturers refunding to DoD the amounts in excess of the Federal Ceiling Prices, manufacturers could reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. This option is not practicable to administer because there is no existing apparatus to identify the very small (relatively) subset of drugs that will end up as prescriptions paid for by TRICARE out of the entire set of drugs that begin the distribution chain through a sale by a manufacturer to a wholesaler. No commenter suggested that such a system would be practicable.

The second alternative option—that TRICARE reduce payments to retail pharmacies by an amount corresponding to a manufacturing cost discount of 24% below the non-Federal average manufacturer price, expecting other arrangements among retail pharmacies, wholesalers, and manufacturers to accommodate those participants' commercial viability—is also not practicable. DoD has no way to manage the implementation of such other arrangements. It is not practicable to expect retail pharmacies to absorb an economic loss in order to remain in the TRICARE Retail Pharmacy Network. No commenter suggested that this alternative option is administratively practicable.

The third alternative option is that DoD authorize pharmacies to purchase drugs directly from manufacturers earmarked for TRICARE beneficiaries

and to do so at the FCP. For example, the retail pharmacy could be authorized to order off the Federal Supply Schedule. This is not practicable because the retail pharmacies would then have to have a separate inventory management system to ensure that those drugs are used only for prescriptions provided to TRICARE beneficiaries, and not diverted to individuals covered by other health plans for whom the manufacturer is not required to provide drugs at the FCP. DoD has no administrative apparatus to ensure that 60,000 network pharmacies strictly maintain such a separate inventory management system, especially considering that TRICARE covered prescriptions are generally a very small fraction of the retail pharmacy's total prescription drug business. No commenter commented that this option would be administratively practicable.

The fourth alternative option—that DoD procure drugs directly from manufacturers at the Federal Ceiling Price and then distribute the drugs to retail pharmacies for use in filling prescriptions to beneficiaries of the plan sponsor—is not practicable because DoD would need to establish a separate distribution system to deliver drugs to more than 60,000 retail pharmacies. Further, such pharmacies would then have to have a separate inventory management system to ensure that these drugs are not provided to non-TRICARE eligible people. It is not practicable for DoD to create separate distribution and inventory management systems for the vast prescription drug retail pharmacy industry, particularly because TRICARE beneficiaries make up a very small portion of the United States population served by that industry. No commenter commented that this alternative option is administratively practicable.

The fifth alternative, the vendor charge-back approach, is not practicable in a very large retail pharmacy network because there is no practicable system for DoD to ensure that the earmarked drugs from the wholesaler would be handled by many thousands of retail pharmacies for the exclusive benefit of TRICARE beneficiaries. No commenter recommended this approach as administratively practicable.

The sixth alternative, the replacement inventory approach, is also not practicable in a very large retail pharmacy network because DoD has no system to audit the inventory replacement for many thousands of retail pharmacies. No commenter recommended this approach.

Thus, the manufacturer refund method is the most administratively practicable system for implementing

FCPs for the TRICARE Retail Pharmacy Program and no commenter suggested that any other system was administratively practicable. In fact, with the exception of arguments made in litigation, the pharmaceutical industry has consistently endorsed manufacturer rebates or refunds as the practicable method of administration, and no commenter recommended otherwise.

(d) *Conclusion on how FCPs are applied.*

DoD's conclusion on how FCPs should apply to the TRICARE Retail Pharmacy Program is that they should apply through a system of manufacturer refunds to DoD of the amount the manufacturer received above the FCP. That system is in harmony with the statute and legislative history, consistent with best business practice in the industry, and administratively practicable. None of the alternative options is comparable based on these criteria and no commenter suggested that any of them be adopted.

3. *When do FCPs apply?*

This was not one of the issues that the Court ordered DoD to reconsider as a matter of DoD's discretionary judgment. However, it was an issue addressed in the Court's ruling and it was the subject of several comments. This issue is: *When do FCPs begin to apply to prescriptions filled in the TRICARE retail pharmacy program?* The Court's order of November 30, 2009, granted judgment in favor of DoD "with respect to the Defense Department's conclusion that 10 U.S.C. 1074g(f) required that the Federal Ceiling Prices apply to any TRICARE retail pharmacy prescriptions filled on or after January 28, 2008." The Court's opinion stated "the precise question is whether the statute's requirement that TRICARE drug prescriptions are subject to the Federal Ceiling Prices—however implemented by the agency—is active on January 28, 2008, or only once DoD promulgates a rule to implement the statute." The Court answered the question by explaining that "the statutory language is clear: 'With respect to any prescription filled on or after the date of the enactment of [NDAA-08], pharmaceuticals purchased through the retail pharmacy program are subject to the Federal Ceiling Prices.'" (Emphasis in the Court's opinion.) The opinion further concludes that "no retroactivity problem is presented" by the final rule because all parties "were aware on January 28, 2008, that 10 U.S.C. 1074g(f) applied the Federal Ceiling Prices to retail pharmacy program transactions as of that date."

DoD understands the Court's conclusion to be that the starting date for applying FCPs to TRICARE Retail Pharmacy Program prescriptions is established by statute and it is not a matter of DoD's discretion in the final rule to establish a different starting date. DoD agrees with this conclusion. However, commenters on behalf of the pharmaceutical industry argue that DoD can and should establish a starting date on or after the effective date of the final rule. Therefore, assuming for the sake of completeness of the rule making record that DoD has discretion to establish a starting date for applying FCPs as of the effective date of the final rule, rather than the effective date of the statute, DoD has considered that alternative option.

(a) *Assessment of options for harmony with the statute and legislative history concerning when FCPs apply.*

Under this criterion, DoD agrees with the Court that "the statutory language is clear." Moreover, the primary statement of legislative history of this section of NDAA-08, the accompanying Conference Report, expressly stated Congressional intent that "the implementation date" is "the date of enactment of this Act." (H.Conf. Rept. No. 110-477, page 938.) Thus, the option of a start date as of the date of enactment of NDAA-08 is in harmony with the statute and legislative history, and the alternative option of a starting date as of the effective date of the final rule is not.

(b) *Assessment of options for consistency with best business practice concerning when FCPs apply.*

Pharmaceutical industry commenters asserted that standard business practice requires that arrangements concerning price be adopted prospectively and that it is unfair to change those arrangements after the fact. However, DoD believes this standard was met with respect to NDAA-08 because everyone was on notice that FCPs applied as of the date of enactment. Further, DoD sent a "Dear Pharmaceutical Manufacturer" letter to each manufacturer three days after the date of enactment of the law, providing them with a copy of the applicable section as well as DoD's interpretation making clear that DoD believed the law to apply to manufacturer prices as of the date of statutory enactment. Moreover, the proposed rule also stated that FCPs apply to any prescription filled on or after the date of statutory enactment. It is also noteworthy that NDAA-08 followed a four year running debate between the government and the pharmaceutical industry over the issue of applying FCPs to the TRICARE Retail Pharmacy Program, a debate that

included prior litigation and Congressional consideration. Thus, no one associated with the pharmaceutical industry could have been unaware. Finally on this point, DoD included in the final rule a procedure for waiver or compromise of refund amounts to permit consideration of any particular circumstances where implementation as of the statutory effective date would be insupportable. On this criterion, DoD concludes that the statutory effective date option is consistent with best business practice of establishing prospective terms for transactions.

(c) *Assessment of options for practicability of administration concerning when FCPs apply.*

Based on the data systems that have been in use and the pre-existing VARRS process for retail rebates, both options—the statutory effective date option and the final rule effective date option—are administratively practicable.

(d) *Conclusion on when FCPs apply.*

On this issue, DoD has concluded that the statutory effective date option is the right one to adopt because it is in harmony with the statute and legislative history, whereas the final rule effective date option is not; it is consistent with best business practice; and it is on par with the final rule effective date option regarding administrative practicability.

4. *To what do FCPs apply?*

This also is not an issue the Court ordered DoD to reconsider as a matter of DoD's discretion. However, commenters on behalf of the pharmaceutical industry recommended that DoD reconsider it. The industry recommendation is that DoD not apply FCPs to *all* covered prescriptions filled through the TRICARE Retail Pharmacy Program and paid for by DoD, but only those prescriptions covered by prospective procurement contracts between DoD and the manufacturer or comparable agreements having certain attributes they associate with procurement contracts. The Court's November 30, 2009, opinion rejected the argument that the statute required a procurement-type contract as a precondition to applying FCPs, but considered this option to be within the scope of DoD's discretionary judgment as to implementation method.

DoD has considered two options on the issue of what prescriptions are to be covered by manufacturer refunds: (1) All covered prescriptions; and (2) only those prescriptions covered by procurement-type contracts or agreements. The 2009 final rule applied to *all* covered drug prescriptions, subject to a voluntary opt-out and a waiver/compromise process. Covered

drugs for this purpose are drugs covered by 38 U.S.C. 8126, paid for by DoD, introduced by the manufacturer into the normal supply chain, and dispensed to a TRICARE beneficiary by a network retail pharmacy. The final rule excluded drugs not covered by § 8126, drugs for which TRICARE was not primary payer, drugs provided through the 340B program, and (based on legislative history and administrative practicability) non-network pharmacy dispensed drugs.

The procurement-type contract option, as presented by commenters, would require a prospective written contract or agreement stating that in return for FCP-based refunds/rebates the manufacturer would receive favorable positioning on the uniform formulary, and that prescriptions filled in the TRICARE Retail Pharmacy Program for drugs not covered by such an agreement would be exempt from FCPs. (Some commenters asserted that the 2008 proposed rule was consistent with this option, but this is incorrect as both the 2008 proposed rule and the 2009 final rule required the application of FCPs to any prescription filled on or after the date of enactment and incorporated the regulatory overpayment recovery procedures of 32 CFR 199.11 for all such prescriptions.)

(a) *Assessment of options for harmony with the statute and legislative history concerning FCP applicability.*

As noted above, the statute provides:

With respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

Section 8126 of title 38 is titled, "Limitation on prices of drugs procured by Department and certain other Federal agencies." The Department referred to is the Department of Veterans Affairs and the other agencies include DoD. The statute requires that as a condition of doing business under covered Federal programs, "[e]ach manufacturer of covered drugs shall enter into a master agreement with the Secretary" of Veterans Affairs under which "with respect to each covered drug of the manufacturer procured by a [covered] Federal agency * * * the manufacturer has entered into and has in effect a pharmaceutical pricing agreement

* * * under which the price charged * * * may not exceed 76 percent of the non-Federal average manufacturer price." The price referred to in this statute is the Federal Ceiling Price. The purpose and effect of section 8126, as applied to DoD, is that all covered drugs procured by DoD are subject to the Federal Ceiling Price.

Pharmaceutical industry commenters asserted that the "procurement of drugs" phrase in § 1074g(f) requires implementation through procurement-type contracts. They commented that this position is supported by the construct of § 8126, which requires an agreement and that the application of FCPs without such a contract would be to treat the TRICARE Retail Pharmacy Program better than other elements of DoD under § 8126. They further pointed to § 8126(g)(2), which they say freezes the statute's requirements in place as of the date of enactment, giving the resulting pharmaceutical pricing agreement precedence over later statutory enactments and their implementing regulations.

DoD does not agree that these views are in harmony with the statute and legislative history. The "procurement of drugs" phrase in § 1074g(f) is to identify the applicability of § 8126 and to establish the applicability of § 8126 as the purpose for which the TRICARE retail pharmacy program shall be treated as an element of DoD. That purpose is to bring it within the scope of the requirement of § 8126 "to the extent necessary to ensure that pharmaceuticals paid for by" DoD through the TRICARE retail pharmacy program "are subject to the" FCP "pricing standards." The "procurement of drugs" phrase does not in § 1074g(f) describe the *transaction* to which the FCP requirement attaches. Rather, the transaction to which the FCP requirement attaches is clearly established as a "prescription filled" for a drug "paid for by" DoD "provided by" a program pharmacy "to eligible covered beneficiaries." The procurement-type contract option requires that the phrase "procurement of drugs" in § 1074g(f) be treated as the TRICARE Retail Pharmacy Program *transaction* to which the FCP requirement attaches. This would treat the statute as if it read:

With respect to any *procurement of drugs by the TRICARE retail pharmacy program* [rather than "any prescription filled"] on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal

agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals *procured by the TRICARE retail pharmacy program* [rather than "paid for by the Department of Defense"] that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

This is not in harmony with what Congress actually enacted. It would not cover "any prescription filled," but only some prescriptions filled. It would not "ensure that" pharmaceuticals paid for by DoD are subject to FCPs; it would exempt prescriptions paid for by DoD but not covered by a procurement-type contract. And it would not provide that the retail pharmacy program "shall" be treated as an element of DoD for purposes of FCP applicability, only that it may be so treated if that is provided for in a procurement-type contract.

The pharmaceutical industry's argument on § 8126(g)(2) also does not have weight. What this paragraph actually says is that a manufacturer meets its obligation under that law if it "establishes to the satisfaction of the Secretary" of Veterans Affairs that the manufacturer is complying with § 8126 as enacted, without regard to a future legislative change in that section. DoD has seen no evidence that the Secretary of Veterans Affairs has determined that anything in § 1074g(f) or the 2009 final rule is beyond the scope of § 8126. Rather, it is DoD's understanding that the position of the Secretary of Veterans Affairs continues to be that the TRICARE Retail Pharmacy Program is covered by § 8126. (In the preamble to the 2009 final rule, DoD suggested that DoD and the pharmaceutical industry should "agree to disagree" on whether the TRICARE Retail Pharmacy Program is covered directly by § 8126 since that issue was beyond the scope of the final rule and DoD authority, and it would be a moot point if manufacturers complied with the final rule.)

Nor is the procurement-type contract option in harmony with the legislative history of what Congress enacted. The Conference Report accompanying NDAA-08 described the applicable section as a provision "that would require that any prescription filled * * * through the TRICARE retail pharmacy network will be covered by the Federal pricing limits applicable to covered drugs under section 8126 of title 38, United States Code." (H. Conf. Rept. 110-477, p. 938.) In addition, a very similar provision that was passed by the Senate in its proposed version of NDAA-07 but not finally enacted at that

time (“The TRICARE Retail Pharmacy Network * * * shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 * * *.”) was described in the accompanying Senate Committee Report as a provision to “reaffirm a decision made by the Secretary of Veterans Affairs on October 24, 2002, * * * that drugs purchased by the Department of Defense through the TRICARE retail pharmacy network are subject to the same Federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program.” (S. Rept. No. 109–254, pp. 342–43.) Thus, the all covered prescriptions option is in harmony with the statute and legislative history; the procurement-type contract option is not.

In addition to the pre-enactment legislative history, recent Congressional commentary reinforces this understanding of Congressional expectations. For example, the Senate Appropriations Committee report accompanying the Department of Defense Appropriations Bill, 2010, expressed concern that “the fiscal years 2008 and 2009 budgetary savings programmed by the Department of Defense and the Office of Management and Budget for manufacturer refunds for TRICARE retail pharmacy prescriptions under section 703 of the National Defense Authorization Act for Fiscal Year 2008 have not been realized,” and asked for a report from DoD on implementation, “including an assessment of whether any additional legislation is needed to effectuate the purposes of section 703.” (S. Rept. No. 111–74, p. 224.) (The resulting DoD report advised that no additional legislation is needed.) The House Appropriations Committee expressed similar concern, noting “the \$1,000,000,000 in rebates that are currently owed.” (H. Rept. No. 111–230, p. 307.)

(b) *Assessment of options for consistency with best business practice concerning FCP applicability.*

Commenters on behalf of the pharmaceutical industry assert that best business practice calls for the voluntary agreement of the parties and that only a procurement-type contract is consistent with this practice. But the all covered prescriptions option also provides for the voluntary agreement of the parties; no pharmaceutical manufacturer is forced to do business with DoD under 10 U.S.C. 1074g or other agencies under 38 U.S.C. 8126. Manufacturers make a voluntary choice

to do business with DoD under the applicable terms. The difference between the two options is not in the *nature* of the voluntary participation, it is in the *terms* of the voluntary participation. The procurement-type contract option seeks more limited *terms*, such as that FCPs will only apply if drugs receive *preferred* status under the uniform formulary, rather than *covered* status. The 2009 final rule attaches FCP applicability to a voluntary decision by the manufacturer to keep its drugs covered by TRICARE, rather than take the opt-out opportunity provided in the rule. Voluntariness is preserved under both options. Under the all covered prescriptions option, preferred formulary status is based on cost-effectiveness, which means a price no higher than the FCP, and for drug classes that have competition among covered drugs, generally a price below the FCP. Taking advantage of competition in drug classes to produce prices below FCP (*i.e.*, refunds greater than the FCP-level refund) is more consistent with best business practice. All of this has to do with the *terms* of doing business, not with the nature of the business practice.

(c) *Assessment of options for practicability of administration concerning FCP applicability.*

Both options rely upon the same implementation apparatus, so both options are administratively practicable.

(d) *Conclusion on the issue of to what do FCPs apply.*

DoD has concluded that the option that all covered drug TRICARE retail pharmacy network prescriptions are subject to FCPs is the better option because: It is in harmony with the statute and legislative history, while the alternative, procurement-type contract option is not; it is more consistent with best business practice; and it is comparable in administrative practicability.

C. Additional Issues Raised by Public Comments

What follows is a brief summary of the 2009 final rule and a discussion of the new public comments received pertinent to those provisions. The 2009 final rule added to section 199.21 of the TRICARE regulation, the section governing the Pharmacy Benefits Program, a new paragraph (q) regarding pricing standards for the retail pharmacy program.

1. Section 199.21(q)(1).

As in paragraph (1) of the 2008 proposed rule, paragraph (1)(i) of the 2009 final rule repeated the statutory requirement, virtually verbatim. Like

the statute, both the proposed and final rules applied FCPs to “any prescription filled on or after the date of the enactment” of the statute. Paragraph (1)(ii) was added in the 2009 final rule to state in simpler terms (similar to the primary statement in the legislative history of § 1074g(f)) DoD’s interpretation of the statute as requiring that all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to FCPs.

Applicability of FCPs to All Covered Drug Prescriptions (Para. (q)(1)(ii))

Comment: Pharmaceutical industry commenters recommended an exemption, which could potentially be added to this paragraph, for prescriptions filled after January 28, 2008, but covered by pre-existing Uniform Formulary Voluntary Agreements for Retail Refunds (UF–VARRs) that provided for less than FCP-based discounts, the exemption lasting as long as necessary to implement the termination clause of the VARR. The rationale was that this would show appropriate deference to the terms of the pre-existing agreements.

Response: For the reasons given above relating to the starting date for applying FCPs under the statute, DoD has concluded that the final rule should not be changed, and that it should, as the proposed rule did, mirror the statute’s applicability to “any prescription filled on or after the date of enactment.” The statutory effective date, of which everyone had notice, obviated the need for DoD to cancel the pre-existing UF–VARRs, which also could have been canceled at any time by the manufacturer. The applicability of FCPs on or after January 28, 2008, is not dependent on Tier 2 Uniform Formulary status or the existence of a VARR or pricing agreement. If there is some special circumstance regarding any particular drug, it can be addressed under the waiver/compromise authority of paragraph (q)(3)(iii).

2. Section 199.21(q)(2).

Paragraph (q)(2) provided, similar to the proposed rule, that a written agreement by a manufacturer to honor Federal Ceiling Prices in the retail pharmacy network is with respect to a particular covered drug a condition for inclusion of that drug on the uniform formulary (Tier 2, or in the case of covered generic drugs, Tier 1) and for the availability of that drug through retail network pharmacies without preauthorization.

Preauthorization of Tier 3 Drugs (Para. (q)(2)(ii))

Comment: Pharmaceutical industry commenters recommended removal of the requirement that drugs not covered by voluntary pricing agreements and thus disqualified from Tier 2 uniform formulary status also become subject to preauthorization for dispensing at the retail pharmacy. The argument was made that this preauthorization conflicts with other preauthorization requirements in the TRICARE Pharmacy Benefits Program regulation.

Response: There is no conflict. There are simply two different types of preauthorization. One type of prior authorization relates to *whether* a patient needs a particular drug. The preauthorization required under this paragraph relates to *where* the patient should receive it. If the manufacturer refuses to comply with the requirement to apply FCPs at the retail venue, TRICARE will consider other options to meet the patient's needs, which may include dispensing that same drug at the mail order venue.

Comment: Retail pharmacy industry commenters also recommended elimination of the prior authorization requirement on the grounds that it potentially shifts business from retail pharmacies to the mail order pharmacy and that DoD should force manufacturers to honor FCPs without disadvantaging retail pharmacies.

Response: DoD hopes it will not be necessary to rely on either Tier 3 status or the preauthorization process to reinforce the FCP requirement under paragraph (q), but is unable at this point to forgo the option, when needed. Therefore, this provision is retained in the new final rule.

Inclusion of Authorized Generics as "Covered Drugs" (Para. (q)(2)(iii))

Comment: Pharmaceutical industry commenters recommended exclusion of authorized generics from the definition of covered drugs. Authorized generics are drugs that were approved by the Food and Drug Administration under a new drug application (NDA), rather than an abbreviated new drug application (ANDA) under section 505(j) of the Food, Drug, and Cosmetic Act, and are still marketed under the original NDA approval, but are no longer single source drugs. The rationale was that generic drug competition usually produces a low price and it is unfair to impose an additional FCP-based discount to the authorized generics when their competitor ANDA generics have no such requirement.

Response: With awareness of the statutory reference to "the pricing

standards in * * * section 8126," the 2009 final rule maintained the section 8126 definition of covered drugs. Covered drugs, including authorized generics, are subject to FCPs under section 8126 and are sold at the FCP (or FSS price if lower) for prescriptions filled at military facility pharmacies and the mail order pharmacy program. In regard to the economics of authorized generics, manufacturers still have marketing options to protect profits. In any event, the Department of Veterans Affairs, the lead agency for FCP implementation government-wide, has not recommended exemption of authorized generics as covered drugs, and DoD has concluded that following the lead agency's policy on this is advisable. Therefore, the new final rule is unchanged on this point.

Exclusion of 340B Drugs (Para. (q)(2)(iii)(E))

Comment: Pharmaceutical industry commenters recommended the continued exclusion of 340B program drugs.

Response: This provision is unchanged in the new final rule. They are excluded.

Comment: Commenters on behalf of specialty providers under the 340B program agreed that 340B covered drugs should be excluded from covered drugs under this rule, but expressed concern that this might be causing their newly restricted ability to participate in the TRICARE Retail Pharmacy Network.

Response: DoD is aware of and seeking to address issues between some of these providers, such as comprehensive hemophilia treatment centers, and TRICARE's Pharmacy Benefits Manager contractor. These issues, however, are not affected by the exclusion of 340B program drugs from this final rule and thus are outside the scope of this rulemaking.

3. Section 199.21(q)(3).

Paragraph (q)(3) of the 2009 final rule addressed refund procedures. As under the proposed rule, paragraph (q)(3)(iii) of the 2009 final rule stated that a refund due under the final rule is subject to section 199.11 of the TRICARE regulation, the section that governs "overpayments recovery." The 2009 final rule was revised to elaborate that the applicability of section 199.11 brings with it a procedure for a manufacturer to request waiver or compromise of a refund amount. Also, in response to pharmaceutical industry complaints that the rule would make the imposition of FCPs involuntary on manufacturers since they could not control the flow of their products

through the supply chain that end up as prescriptions filled under the TRICARE Retail Pharmacy Program, the 2009 final rule was revised to state that a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program. Based on such a voluntary opt-out, DoD could block the prescription at the retail network pharmacy and in other transactions pertinent to the military facility pharmacies and mail order pharmacy, thus preserving the manufacturer's voluntary choice on whether it wants to participate in the TRICARE Pharmacy Benefits Program.

FCP Calculation (Para. (q)(3)(ii))

Comment: Pharmaceutical industry commenters suggested that DoD apply an alternative Federal Ceiling Price under this rule, one that would not include the computation under § 8126(d)(1) that is referred to as the "FSS Max Cap."

Response: Under paragraph (q)(3)(ii), DoD applies the FCP as it is calculated and provided by the Department of Veterans Affairs (DVA). The DVA's calculations in second and subsequent years of multi-year contracts take into account prices reflected in those contracts, referred to as the FSS Max Cap. In those years the resulting FCP is applicable to all covered drug contracts and applicable to the TRICARE Retail Pharmacy Program. Based on this comment, DoD considered asking DVA to produce an alternative set of FCPs for the TRICARE Retail Pharmacy Program that would exclude any impact of the FSS Max Cap. Assuming the technical feasibility of this option, it was considered under the same criteria used for the major issues assessed in this rulemaking reconsideration process. With respect to consistency with the statute and legislative history, there is clear legislative history that Congress intended "that drugs purchased by the Department of Defense through the TRICARE retail pharmacy network are subject to the same federal pricing limits that have long applied to drugs purchased by the Department and provided through military hospitals and clinics and the national mail order program." S. Rept. 109-254, pp. 342-343. The use of two sets of FCPs—one for military facilities and the mail order program and a different set for the retail program—would conflict with this Congressional intent. In addition, with respect to administrative practicability, there is currently only one set of FCPs calculated by DVA, and while it is not impossible to calculate an alternative set of FCPs, doing so for one segment of

covered drugs for one of the “big four” agencies covered by section 8126 could create confusion and administrative difficulties. Further, in connection with implementation of the 2009 final rule to date and the voluntary agreements made under it, DoD is unaware of any request from a manufacturer for use of anything other than the normal FCPs, nor of any request from a manufacturer for a waiver or compromise of the refund amount based on the possible effect on the FCPs of the FSS Max Cap. Were there special circumstances relating to application of the FCP in a particular case, the compromise process would be the appropriate one to find a remedy. Based on these considerations, it is DoD’s judgment that the single set of FCPs calculated by DVA under section 8126 apply to the TRICARE Retail Pharmacy Program as they do to the TRICARE Pharmacy Benefits Program generally.

Overpayments Recovery Procedures (Para. (q)(3)(iii)(A))

Comment: Pharmaceutical industry commenters recommended deletion of the provision stating that the normal TRICARE overpayments recovery procedures of 32 CFR 199.11 would apply to retail refunds due under § 199.21(q), or revision to limit overpayments recovery to refunds owed under contracts. Comments argued that properly constructed voluntary refunds do not fit the purposes and scope of § 199.11.

Response: DoD believes § 199.11, which has been incorporated by reference since the proposed rule, is properly used for all refunds under § 199.21(q), all of which are based on the voluntary decision of the manufacturer to participate in TRICARE. Section 199.11 applies to “erroneous payments,” which are “expenditures of government funds which are not authorized by law or this part” (*i.e.*, Part 199, the TRICARE Regulation). Because this final rule is intended, in the terms used in the statute, to ensure that covered prescriptions are subject to the FCP pricing standards, it fits § 199.11 very well to view the amount paid that exceeds FCPs as an expenditure of government funds in excess of the amount authorized by the TRICARE regulation, specifically § 199.21(q), which in turn is authorized by the statute.

Opt-Out Provision (Para. (q)(3)(iii)(C))

Comment: Pharmaceutical industry commenters recommended that remedial actions continue to be on a drug-by-drug basis, rather than a

company-by-company basis, to give manufacturers flexibility on deciding whether they wish to do business with TRICARE.

Response: The opt-out provision continues to be on a drug-by-drug basis. A manufacturer is not required by this regulation to remove all of its drugs from TRICARE coverage in order to remove any. However, DoD makes no representation that selective opt-outs would be consistent with the manufacturer’s obligations under its § 8126 master agreement, a matter which is outside DoD’s authority.

Comment: Pharmaceutical industry commenters commented that manufacturers should be given notice and an opportunity to opt-out in order to avoid liability for prescriptions filled prior to the effective date of the regulation.

Response: The opt-out opportunity has been available since the effective date of the 2009 final rule, May 26, 2009. The 2009 final rule provided for “the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.” To date, no manufacturer has opted out. DoD takes this as a voluntary agreement to participate in the TRICARE Pharmacy Benefits Program under the terms of the TRICARE Regulation. The opt-out opportunity remains available under this new final rule, and it may be coupled with a request for waiver or compromise.

Comment: Pharmaceutical industry commenters asserted that in the absence of a voluntary agreement between a manufacturer and DoD, a refund requirement conflicts with the Unfunded Mandates Reform Act.

Response: This program is neither unfunded nor a mandate. The opt-out provision ensures that the application of FCPs is a function of the voluntary decision of manufacturers to participate in the TRICARE Pharmacy Benefits Program under the terms required or authorized by statute, including 10 U.S.C. 1074g(f). The economic impact of this regulation is not in the nature of a mandatory expenditure by the private sector, but in the nature of reduced Federal expenditures for pharmaceuticals paid for by DoD under TRICARE, which is precisely what Congress intended.

Comment: Pharmaceutical industry commenters argued that the opt-out authority should allow manufacturers to opt out of the Retail Pharmacy Program only, rather than opt out of the entire TRICARE Pharmacy Benefits Program. They argued that if they opt out of the TRICARE Pharmacy Benefits Program

completely, this will put them in violation of their master agreement with the Department of Veterans Affairs, which includes a requirement to make their products available under the Federal Supply Schedule to DoD.

Response: Again, this is a discussion over *terms* of voluntary participation in the TRICARE Pharmacy Benefits Program, not over the nature of voluntary participation. If the pharmaceutical industry is correct that 39 U.S.C. 8126(g)(2) (which is discussed above) freezes their § 8126 obligations as of the original enactment of that law and that this TRICARE rule creates new obligations beyond the scope of § 8126, they will be able to remain in compliance with § 8126 by demonstrating a willingness to adhere to the original scope of obligations, including a willingness to make their drugs available under the Federal Supply Schedule. If the industry is not correct about that (which DoD believes to be the case), manufacturers remain free voluntarily to decide whether they want to do business with all agencies covered by § 8126 under the terms Congress has established or authorized. For doing business with DoD, DoD believes the terms of voluntary participation are properly set as honoring FCPs in all three venues of the TRICARE Pharmacy Benefits Program—military facility pharmacies, mail order pharmacy, and retail pharmacy network. DoD understands that manufacturers would prefer more favorable terms, but these terms are in harmony with the statute and legislative history, consistent with best business practice, and administratively practicable.

4. Section 199.21(q)(4), Remedies.

Paragraph (q)(4) of the 2009 final rule provided that in the case of the failure of a manufacturer of a covered drug to make or honor an agreement under paragraph (q), DoD may take any action authorized by law. This paragraph was unchanged from the 2008 proposed rule.

Comment: Pharmaceutical industry commenters recommended deletion of the provision stating that in the case of the failure of a manufacturer “to make” an agreement under paragraph (q), DoD may take any other action authorized by law on the grounds that the only appropriate remedy would be under breach of contract rules concerning an agreement that had been voluntarily made.

Response: DoD believes the authority to take any action authorized by law, which has been included since the proposed rule, is properly used for all obligations under the regulation, all of which are based on the voluntary

decision of the manufacturer to participate in the TRICARE Retail Pharmacy Program. However, the point is well taken that under the rule, a failure “to make” an agreement is not an action that should be treated as noncompliance nor be the subject of a remedy. This is because the applicability of FCPs is not dependent upon the making of an agreement. Rather, it is a function of the voluntary decision of a manufacturer to continue to participate in the TRICARE Pharmacy Benefits Program, rather than to take advantage of the opt-out opportunity. Therefore, this paragraph has been revised. The revised paragraph no longer premises a remedy on a failure “to make or honor an agreement under” paragraph (q), but on a failure “to honor a requirement of” paragraph (q) or “to honor an agreement under” paragraph (q). An accompanying revision is also made to paragraph (q)(3)(iii)(B) to state that during the pendency of a request for waiver or compromise of a refund amount, the matter that is the subject of the request will not be treated as a failure to honor a requirement of paragraph (q).

5. Section 199.21(q)(5).

Finally, paragraph (q)(5) of the 2009 final rule authorized beneficiary transition provisions to protect beneficiary access to particular pharmaceuticals even when manufacturers act to avoid the application of FCPs. No comments were received during this new comment period regarding this provision.

D. Provisions of New Final Rule

DoD is readopting the 2009 final rule, with one substantive change and another accompanying revision. The substantive change is to paragraph (q)(4) concerning remedies. An accompanying change is to paragraph (q)(3)(iii)(B) concerning the effect of a pending request for waiver or compromise of a refund amount. Following is a summary of the new final rule.

Section 199.21(q) establishes pricing standards for the retail pharmacy program. Paragraph (1) restates the statutory requirement. With respect to any prescription filled on or after the statutory effective date (January 28, 2008), all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices. Paragraph (1) is unchanged from the 2009 final rule. Paragraph (1) answers the question, “When do FCPs apply?” They apply to all prescriptions filled on or after the date of statutory enactment.

Paragraph (2) states that a manufacturer’s written agreement to

honor the requirement of paragraph (1) is a condition for including a drug on the preferred tier (Tier 2, or in the case of covered drugs that are generics, Tier 1) of the uniform formulary and the availability of that drug through retail network pharmacies without preauthorization. As under the 2008 proposed rule and the 2009 final rule, an agreement to honor FCPs does not guarantee preferred tier placement because FCPs are a ceiling price and the cost-effectiveness standard for Tier 2 (and in some cases Tier 1) placement may result in the FCP being insufficiently cost-effective in particular drug classes. Also as under the 2008 proposed rule and the 2009 final rule, the application of FCPs is not conditional on preferred formulary status. Paragraph (2) also defines covered drugs for purposes of the applicability of FCPs. Paragraph (2) is unchanged from the 2009 final rule. This paragraph (2), along with paragraph (3), answer the questions, “Who bears the burden of FCPs?” and “How do FCPs apply?” Manufacturers bear the burden of FCPs, and they apply through manufacturer refunds.

Paragraph (3) establishes refund procedures. Such procedures may be included in an agreement under paragraph (2) or a separate agreement or default to the standard overpayments recovery procedures of the TRICARE regulation, § 199.11. Also under § 199.11, a manufacturer may request a waiver or compromise of a refund amount due. While a waiver or compromise request is pending, the matter that is the subject of the request will not, under revised wording of this paragraph, be treated as a failure to honor a requirement of paragraph (q) for purposes of DoD pursuing any remedies under paragraph (4). Also under paragraph (3), in addition to other grounds for waiver or compromise, a waiver request may be based on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefits Program. This paragraph (3) answers the question, “To what do FCPs apply?” They apply to all covered drugs the manufacturer has voluntarily chosen to keep in the TRICARE Pharmacy Benefits Program.

Paragraph (4) provides that remedies may be based on any action authorized by law. Paragraph (4) is changed from the 2009 final rule. The revised paragraph no longer promises a remedy on a failure “to make or honor an agreement under” paragraph (q), but on a failure “to honor a requirement of” the regulation “or to honor an agreement under” the regulation. This change reinforces that a manufacturer’s failure

“to make an agreement” is not subject to a remedial action because the applicability of FCPs is not dependent upon the “making” of an agreement. Rather, a remedy could be based on a failure to honor a requirement under the final rule for a manufacturer who has made the voluntary decision to participate in the TRICARE Pharmacy Benefits Program by not exercising the opt-out opportunity.

Paragraph (5) authorizes special beneficiary transition provisions for the continued availability of pharmaceuticals to beneficiaries. Paragraph (5) is unchanged from the 2009 final rule.

E. Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review”

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of \$100 million or more in any one year. The DoD has examined the economic, legal, and policy implications of this final rule and has concluded that it is an economically significant regulatory action under section 3(f)(1) of the EO. The economic impact of applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network is in the form of reducing the prices of drugs paid for by DoD in the retail pharmacy component of the TRICARE Pharmacy Benefits Program, making them comparable to the prices paid by DoD in the Military Treatment Facility and Mail Order Pharmacy components of the program.

A recent Government Accountability Office Report, “DoD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies,” April 2008 (GAO–08–327), found that DoD’s drug spending “more than tripled from \$1.6 billion in fiscal year 2000 to \$6.2 billion in fiscal year 2006” and that retail pharmacy spending “drove most of this increase, rising almost nine-fold from \$455 million to \$3.9 billion and growing from 29 percent of overall drug spending to 63 percent.” DoD concurs in these findings. The principal economic impact of this final rule is to moderate somewhat the rate of growth in spending in the retail pharmacy component of the program.

At various times since the enactment of NDAA–08, DoD estimated the reduced spending associated with applying Federal Ceiling Prices to the Retail Pharmacy Network. DoD funds the Military Health System through two separate mechanisms. One is the

Defense Health Program (DHP) appropriation, which pays for health care for all beneficiaries except those who are also eligible for Medicare. DoD-funded health care for DoD beneficiaries who are also eligible for Medicare is paid for by way of an accrual fund called the Medicare-Eligible Retiree Health Care Fund (MERHCF) under 10 U.S.C. chapter 56. Funds are paid into the MERHCF from military personnel appropriations and the general U.S. treasury. At the time of the 2008 proposed rule, for example, DoD estimated FY-10 reduced spending of \$388 Million for the DHP and \$404 for the MERHCF. At the time of the 2009 final rule, DoD used a different estimating model and estimated much larger savings, including for FY-10 for example, reduced spending of \$761 Million for the DHP and \$910 for the MERHCF. Based on experience since issuance of the final rule and a refined estimating model, DoD now estimates that the reduced spending will be closer to the original, lower estimates. DoD's current estimated cost reductions from applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network in Fiscal Years 2010 through 2015 appear in the following table. FCP savings estimates will continue to be updated as actual refunds are received and estimating methodologies are refined.

| Millions of Dollars | |
|---------------------------------------|-----|
| FY-2010 DHP Reduced Spending | 375 |
| FY-2010 MERHCF Reduced Spending | 474 |
| FY-2011 DHP Reduced Spending | 434 |
| FY-2011 MERHCF Reduced Spending | 549 |
| FY-2012 DHP Reduced Spending | 458 |
| FY-2012 MERHCF Reduced Spending | 579 |
| FY-2013 DHP Reduced Spending | 490 |
| FY-2013 MERHCF Reduced Spending | 619 |
| FY-2014 DHP Reduced Spending | 523 |
| FY-2014 MERHCF Reduced Spending | 661 |
| FY-2015 DHP Reduced Spending | 560 |
| FY-2015 MERHCF Reduced Spending | 707 |

As a frame of reference, total TRICARE Pharmacy Benefits Program spending is estimated to be \$8.5 billion in FY-2010.

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts. This final rule is a major rule

under the Congressional Review Act. As noted above, applying Federal Ceiling Prices to the TRICARE Retail Pharmacy Network will reduce DoD spending on pharmaceuticals by more than \$100 million per year.

Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year. The economic impact of this regulation, described above, is not in the form of a mandated expenditure by a State, local, or tribal government or the private sector, but by reduced Federal expenditures.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. DoD does not anticipate that this regulation will result in changes that would impact small entities, including retail pharmacies, whose reimbursements are not affected by the final rule. In addition, drugs newly subject to implementation of Federal Ceiling Prices under the final rule represent less than 2% of manufacturers' prescription drug sales. Therefore, this final rule is not expected to result in significant impacts on a substantial number of small entities.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This final rule contains information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3511). This consists of responding to the periodic TMA report of the TRICARE prescription utilization data needed to calculate the refund. This information collection has been approved with OMB Control Number 0720-0032. No person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

Executive Order 13132, "Federalism"

This final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the

States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Health care, Health insurance, Military personnel, Pharmacy benefits.

■ Accordingly, 32 CFR part 199 is amended as follows:

PART 199—[AMENDED]

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Section 199.21(q) is revised to read as follows:

§ 199.21 Pharmacy benefits program.

* * * * *

(q) *Pricing standards for retail pharmacy program—(1) Statutory requirement.* (i) As required by 10 U.S.C. 1074g(f), with respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the DoD for purposes of the procurement of drugs by Federal agencies under 38 U.S.C. 8126 to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

(ii) Under paragraph (q)(1)(i) of this section, all covered drug TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126.

(2) *Manufacturer written agreement.*

(i) A written agreement by a manufacturer to honor the pricing standards required by 10 U.S.C. 1074g(f) and referred to in paragraph (q)(1) of this section for pharmaceuticals provided through retail network pharmacies shall with respect to a particular covered drug be a condition for:

(A) Inclusion of that drug on the uniform formulary under this section; and

(B) Availability of that drug through retail network pharmacies without preauthorization under paragraph (k) of this section.

(ii) A covered drug not under an agreement under paragraph (q)(2)(i) of this section requires preauthorization under paragraph (k) of this section to be provided through a retail network pharmacy under the Pharmacy Benefits

Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126, but does not include:

(A) A drug that is not a covered drug under 38 U.S.C. 8126;

(B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074g(f);

(C) A drug that is not provided through a retail network pharmacy under this section;

(D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;

(E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or

(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) *Refund procedures.* (i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to § 199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed

to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to § 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074g(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under paragraph (q)(3)(iii)(A) of this section, a manufacturer's written agreement under paragraph (q)(2) shall be deemed to exclude the matter that is the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor a requirement or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in § 199.11, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.10 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in

dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) *Remedies.* In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) *Beneficiary transition provisions.* In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.

Dated: October 7, 2010.

Morgan F. Park,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2010-25712 Filed 10-14-10; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2010-0926]

Drawbridge Operation Regulations; Hackensack River, Jersey City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 1 & 9 Lincoln Highway Bridge across the Hackensack River, mile 1.8, at Jersey City, New Jersey. The deviation allows the bridge owner to require a two-hour advance notice for openings for two and a half months and several short term bridge closures to facilitate bridge painting operations.

DATES: This deviation is effective with constructive notice from October 15, 2010 through December 15, 2010, and for enforcement with actual notice from October 4, 2010 through October 15, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0926 and are available online at <http://www.regulations.gov>, inserting USCG–2010–0926 in the “Keyword” and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Joe Arca, Project Officer, First Coast Guard District, joe.arca@uscg.mil, telephone (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Route 1 & 9 Lincoln Highway Bridge, across the Hackensack River, mile 1.8, at Jersey City, New Jersey, has a vertical clearance in the closed position of 35 feet at mean high water and 40 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.5.

The waterway is primarily used by deep draft tankers, tugs and barge units.

The owner of the bridge, New Jersey Department of Transportation, requested a second temporary deviation from the regulations to facilitate scheduled bridge painting operations at the bridge.

We issued a previous temporary deviation for this bridge painting project which was in effect from April 1, 2010 through September 15, 2010; however, due to weather related delays additional time is needed to complete the bridge painting before the cold winter climate forces suspension of painting operations.

Waterway users were advised of the requested bridge advance notice and closure periods and offered no objection.

Under this temporary deviation the Route 1 & 9 Lincoln Highway Bridge shall require a two-hour advance notice for bridge openings from October 1, 2010 through December 15, 2010, by calling the number posted at the bridge.

In addition, the bridge owner requested several bridge closures of short duration to facilitate bridge painting operations.

The exact bridge closure dates are not known at this time; however, once determined, we will publish the closure dates in the Local Notice to Mariners two weeks in advance of

implementation and also issue a safety information broadcast twenty-four hours in advance of the implementation.

Vessels able to pass under the closed draw may do so at all times.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 4, 2010.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2010–25920 Filed 10–14–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2010–0003; Internal Agency Docket No. FEMA–8153]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community’s scheduled suspension is the third date (“Susp.”) listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA’s initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer

stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management

measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of

information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

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

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

| State and location | Community No. | Effective date authorization/cancellation of sale of flood insurance in community | Current effective map date | Date certain Federal assistance no longer available in SFHAs |
|--|---------------|---|----------------------------|--|
| Region III | | | | |
| West Virginia: | | | | |
| Durbin, Town of, Pocahontas County ... | 540158 | May 13, 1975, Emerg; August 24, 1984, Reg; November 4, 2010, Susp. | Nov. 4, 2010 | Nov. 4, 2010 |
| Pocahontas County, Unincorporated Areas. | 540283 | February 12, 1976, Emerg; October 17, 1989, Reg; November 4, 2010, Susp. |do | Do. |
| Region V | | | | |
| Illinois: | | | | |
| Marshall County, Unincorporated Areas | 170994 | June 8, 1984, Emerg; June 8, 1984, Reg; November 4, 2010, Susp. |do | Do. |
| Toluca, City of, Marshall County | 170460 | July 31, 1975, Emerg; June 1, 1984, Reg; November 4, 2010, Susp. |do | Do. |
| Wenona, City of, Marshall County | 170462 | August 4, 1975, Emerg; December 2, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Ohio: | | | | |
| Hocking County, Unincorporated Areas | 390272 | April 18, 1977, Emerg; November 16, 1990, Reg; November 4, 2010, Susp. |do | Do. |
| Laurelville, Village of, Hocking County .. | 390273 | May 14, 1975, Emerg; November 16, 1995, Reg; November 4, 2010, Susp. |do | Do. |
| Logan, City of, Hocking County | 390274 | July 16, 1975, Emerg; January 17, 1986, Reg; November 4, 2010, Susp. |do | Do. |
| Murray City, Village of, Hocking County. | 390275 | April 26, 1974, Emerg; November 15, 1978, Reg; November 4, 2010, Susp. |do | Do. |
| Pike County, Unincorporated Areas | 390450 | February 18, 1976, Emerg; January 15, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Piketon, Village of, Pike County | 390451 | June 25, 1975, Emerg; January 15, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Waverly, City of, Pike County | 390452 | November 19, 1975, Emerg; January 15, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Region VI | | | | |
| Louisiana: | | | | |
| Broussard, City of, St. Martin Parish | 220102 | July 3, 1975, Emerg; March 16, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Parks, Village of, St. Martin Parish | 220190 | May 8, 1973, Emerg; July 16, 1980, Reg; November 4, 2010, Susp. |do | Do. |
| St. John the Baptist Parish, Unincorporated Areas. | 220164 | February 11, 1974, Emerg; July 16, 1980, Reg; November 4, 2010, Susp. |do | Do. |
| St. Martin Parish, Unincorporated Areas | 220178 | April 26, 1973, Emerg; May 3, 1982, Reg; November 4, 2010, Susp. |do | Do. |
| St. Martinville, City of, St. Martin Parish | 220191 | May 8, 1973, Emerg; December 16, 1980, Reg; November 4, 2010, Susp. |do | Do. |
| New Mexico: | | | | |

| State and location | Community No. | Effective date authorization/cancellation of sale of flood insurance in community | Current effective map date | Date certain Federal assistance no longer available in SFHAs |
|--|---------------|---|----------------------------|--|
| Cimarron, Village of, Colfax County | 350007 | February 3, 1976, Emerg; July 1, 1987, Reg; November 4, 2010, Susp. |do | Do. |
| Colfax County, Unincorporated Areas ... | 350126 | July 8, 1975, Emerg; September 30, 1987, Reg; November 4, 2010, Susp. |do | Do. |
| Raton, City of, Colfax County | 350008 | December 5, 1974, Emerg; March 1, 1986, Reg; November 4, 2010, Susp. |do | Do. |
| Springer, Town of, Colfax County | 350009 | October 15, 1974, Emerg; September 4, 1985, Reg; November 4, 2010, Susp. |do | Do. |
| Texas: | | | | |
| Gray County, Unincorporated Areas | 481222 | February 5, 2001, Emerg; November 4, 2010, Reg; November 4, 2010, Susp. |do | Do. |
| Jourdanton, City of, Atascosa County ... | 480703 | December 5, 1980, Emerg; July 18, 1985, Reg; November 4, 2010, Susp. |do | Do. |
| Pampa, City of, Gray County | 480258 | April 19, 1976, Emerg; September 1, 1987, Reg; November 4, 2010, Susp. |do | Do. |
| Pleasanton, City of, Atascosa County ... | 480015 | February 21, 1975, Emerg; April 1, 1981, Reg; November 4, 2010, Susp. |do | Do. |
| Point Blank, City of, San Jacinto County. | 481528 | January 13, 1995, Emerg; November 4, 2010, Reg; November 4, 2010, Susp. |do | Do. |
| Sabinal, City of, Uvalde County | 481039 | August 14, 2002, Emerg; April 1, 2007, Reg; November 4, 2010, Susp. |do | Do. |
| San Jacinto County, Unincorporated Areas. | 480553 | March 23, 1982, Emerg; September 1, 1987, Reg; November 4, 2010, Susp. |do | Do. |
| Shepherd, City of, San Jacinto County | 480554 | August 18, 1975, Emerg; May 18, 1982, Reg; November 4, 2010, Susp. |do | Do. |
| Uvalde County, Unincorporated Areas .. | 480629 | May 16, 1980, Emerg; August 4, 1987, Reg; November 4, 2010, Susp. |do | Do. |
| Region VII | | | | |
| Nebraska: | | | | |
| Crete, City of, Saline County | 310186 | April 17, 1974, Emerg; October 15, 1982, Reg; November 4, 2010, Susp. |do | Do. |
| Friend, City of, Saline County | 310369 | July 8, 1975, Emerg; September 24, 1984, Reg; November 4, 2010, Susp. |do | Do. |
| Saline County, Unincorporated Areas ... | 310472 | February 3, 1981, Emerg; February 4, 1988, Reg; November 4, 2010, Susp. |do | Do. |
| Swanton, Village of, Saline County | 310188 | August 6, 1975, Emerg; August 19, 1985, Reg; November 4, 2010, Susp. |do | Do. |
| Wilber, City of, Saline County | 310189 | May 27, 1975, Emerg; November 3, 1982, Reg; November 4, 2010, Susp. |do | Do. |
| Region VIII | | | | |
| North Dakota: | | | | |
| Belfield, City of, Stark County | 380116 | July 1, 1975, Emerg; September 5, 1979, Reg; November 4, 2010, Susp. |do | Do. |
| Dickinson, City of, Stark County | 380117 | March 5, 1974, Emerg; June 1, 1978, Reg; November 4, 2010, Susp. |do | Do. |
| South Heart, City of, Stark County | 380647 | July 5, 1983, Emerg; February 19, 1986, Reg; November 4, 2010, Susp. |do | Do. |
| Taylor, City of, Stark County | 380118 | May 16, 1978, Emerg; August 12, 1980, Reg; November 4, 2010, Susp. |do | Do. |
| Region X | | | | |
| Washington: | | | | |
| Bainbridge Island, City of, Kitsap County. | 530307 | August 14, 1975, Emerg; February 5, 1986, Reg; November 4, 2010, Susp. |do | Do. |
| Bremerton, City of, Kitsap County | 530093 | May 27, 1975, Emerg; August 15, 1979, Reg; November 4, 2010, Susp. |do | Do. |
| Kitsap County, Unincorporated Areas ... | 530092 | February 19, 1975, Emerg; May 15, 1980, Reg; November 4, 2010, Susp. |do | Do. |
| Port Orchard, City of, Kitsap County | 530094 | June 10, 1975, Emerg; November 15, 1979, Reg; November 4, 2010, Susp. |do | Do. |
| Poulsbo, City of, Kitsap County | 530241 | June 19, 1974, Emerg; July 2, 1979, Reg; November 4, 2010, Susp. |do | Do. |

*do = Ditto.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp—Suspension.

Dated: October 6, 2010.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation.

[FR Doc. 2010-26051 Filed 10-14-10; 8:45 am]

BILLING CODE 9110-12-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 10-1062; MB Docket No. 08-243; RM-11490]

FM Table of Allotments, Culebra, PR, Charlotte Amalie, and Christiansted, VI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division substitutes Channel 237B for vacant Channel 271B at Charlotte Amalie, Virgin Islands to enable Station WNVE-FM to obtain an authorization on Channel 271A at Culebra, Puerto Rico. The reference coordinates for vacant Channel 237B at Charlotte Amalie are 18-20-36 NL and 64-55-48 WL. To facilitate vacant Channel 237B at Charlotte Amalie, we are substituting Channel 224B for Channel 236B at Christiansted, Virgin Islands and modifying the license of FM Station WJKC to reflect this change. The ultimate permittee of Channel 237B at Charlotte Amalie, will be required to reimburse the licensee of Station WJKC(FM), Christiansted, for its reasonable and prudent costs in changing channels to Channel 237B. Additionally, we grant the application, File No. BMPH-20071211AAQ, that requests the substitution of Channel 271A for Channel 254A at Culebra, and modification of the Station WNVE-FM authorization to reflect the change.

DATES: Effective November 15, 2010.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

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

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MB Docket No. 08-243, adopted June 10, 2010, and released June 14, 2010. The full text of this Commission document is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC.

The complete text of this decision may also be purchased from the

Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, 800-378-3160 or via the company's Web site, <http://www.bcpweb.com>.

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

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

Provisions of the Regulatory Flexibility Act of 1980 does not apply to this proceeding.

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Government Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.
Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

■ As stated in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Virgin Islands, is amended by adding Channel 237B at Charlotte Amalie.

[FR Doc. 2010-25929 Filed 10-14-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 0910131362-0087-02]

RIN 0648-XZ67

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Catching Pacific Cod for Processing by the Inshore Component in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2010 Pacific total allowable catch (TAC) apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), October 13, 2010, through 2400 hrs, A.l.t., December 31, 2010.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The 2010 Pacific cod TAC apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA is 18,687 metric tons (mt), as established by the final 2010 and 2011 harvest specifications for groundfish of the GOA (75 FR 11749, March 12, 2010).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region,

NMFS (Regional Administrator) has determined that the 2010 Pacific cod TAC apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 18,600 mt, and is setting aside the remaining 87 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(i), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the GOA.

After the effective date of this closure the maximum retainable amounts at

§ 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory

Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 11, 2010.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: October 12, 2010.

Carrie Selberg,

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

[FR Doc. 2010-26045 Filed 10-12-10; 4:15 pm]

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Proposed Rules

Federal Register

Vol. 75, No. 199

Friday, October 15, 2010

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

DEPARTMENT OF ENERGY

10 CFR Parts 433 and 435

[Docket No. EERE-2010-BT-STD-0031]

RIN 1904-AB96

Fossil Fuel-Generated Energy Consumption Reduction for New Federal Buildings and Major Renovations of Federal Buildings

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Energy (DOE) is publishing this notice of proposed rulemaking to implement provisions of the Energy Conservation and Production Act, as amended by the Energy Independence and Security Act of 2007 that require DOE to establish revised performance standards for the construction of all new Federal buildings, including commercial buildings, multi-family high-rise residential buildings and low-rise residential buildings. The provisions in this notice of proposed rulemaking specifically address the reduction of fossil fuel-generated energy consumption in new Federal buildings and Federal buildings undergoing major renovations. This proposed rule also addresses how agencies other than the General Services Administration (GSA) may petition DOE for a downward adjustment of the requirements if they believe meeting the full fossil fuel-generated energy consumption reduction level is technically impracticable in light of the specified functional needs for that building.

DATES: Public comments on this proposed rule will be accepted until December 14, 2010. DOE will hold a public meeting on Friday, November 12, 2010, from 9 a.m. to 5 p.m., in Washington, DC. Interested persons who wish to speak at the public meeting should e-mail or phone Ms. Brenda Edwards by 4:30 p.m., Friday, October 29, 2010. DOE must receive a signed

original and an electronic copy of statements to be given at the public meeting before 4 p.m., Friday, November 5, 2010. Additionally, DOE plans to conduct the public meeting via webinar. You can attend the public meeting via webinar, and registration information, participant instructions, and information about the capabilities available to webinar participants will be published on the Building Energy Codes Program's Web site http://www.energycodes.gov/events/doe/fossil_fuels.stm, and/or on the Federal Energy Management Program's Web site http://www1.eere.energy.gov/femp/regulations/notices_rules.html. Participants are responsible for ensuring their systems are compatible with the webinar software.

DOE will accept comments, data, and information regarding this notice of proposed rulemaking (NOPR) before and after the public meeting, but no later than December 14, 2010. If you submit information that you believe to be exempt by law from public disclosure, you should submit one complete copy, as well as one copy from which the information claimed to be exempt by law from public disclosure has been deleted. DOE is responsible for the final determination with regard to disclosure or nondisclosure of the information and for treating it accordingly under the DOE Freedom of Information regulations at 10 CFR 1004.11.

ADDRESSES: You may submit comments, identified by any of the following methods:

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

- *E-mail:* FossilFuelReduct-2010-STD-0031@ee.doe.gov. Include EERE-2010-BT-STD-0031 and/or RIN 1904-AB96 in the subject line of the message.

- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE-2J, Fossil Fuel-Generated Energy Consumption Reduction for New Federal Buildings and Major Renovations of Federal Buildings EERE-2010-BT-STD-0031 and/or RIN 1904-AB96, 1000 Independence Avenue, SW., Washington, DC 20585-0121. Telephone: (202) 586-9138. Please submit one signed paper original. Due to the potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages

respondents to submit comments electronically to ensure timely receipt.

- *Hand Delivery/Courier:* Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE-2J, 1000 Independence Avenue, SW., Washington, DC 20585-0121.

Instructions: All submissions must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking.

Docket: For access to the docket to read background documents or comments received by DOE, go to the U.S. Department of Energy, Forrestal Building, Room 5E-080 (Resource Room of the Federal Energy Management Program), 1000 Independence Avenue, SW., Washington, DC, (202) 586-9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please call Brenda Edwards at (202) 586-2945 for additional information regarding visiting the Resource Room.

FOR FURTHER INFORMATION CONTACT:

Margo Appel, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE-2J, 1000 Independence Avenue, SW., Washington, DC 20585-0121, (202) 586-9495, e-mail: margo.appel@hq.doe.gov, or Ami Grace-Tardy, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC-71, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-5709, e-mail: ami.grace-tardy@hq.doe.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Discussion of Proposed Rule
- III. Reference Resources
- IV. Regulatory Review
- V. Approval by the Office of the Secretary

I. Background

Section 305 of the Energy Conservation and Production Act (ECPA) established energy conservation requirements for Federal buildings (42 U.S.C. 6834). Section 433(a) of the Energy Independence and Security Act of 2007 (Pub. L. 110-140) (EISA) amended section 305 of ECPA and directed that DOE establish regulations that revised Federal building energy efficiency performance standards to require that "[f]or new Federal buildings and Federal buildings undergoing major renovations, with respect to which the

Administrator of General Services is required to transmit a prospectus to Congress under section 3307 of Title 40, in the case of public buildings (as defined in section 3301 of Title 40), or of at least \$2,500,000 in costs adjusted annually for inflation for other buildings,” the “buildings shall be designed so that the fossil fuel-generated energy consumption of the buildings is reduced as compared with such energy consumption by a similar building in fiscal year 2003 (as measured by Commercial Buildings Energy Consumption Survey or Residential Energy Consumption Survey data from the Energy Information Agency), by” specific graduated percentages ranging from 55 percent to 100 percent over a specified period of time beginning in fiscal year 2010 and ending in fiscal year 2030 (42 U.S.C. 6834(a)(3)(D)(i)(I)).

In addition, ECPA as amended by EISA permits DOE upon petition by an agency subject to the statutory requirements, to adjust the applicable numeric reduction requirement “downward with respect to a specific building, if the head of the agency designing the building certifies in writing that meeting such requirement would be technically impracticable in light of the agency’s specified functional needs for that building and” DOE concurs with the agency’s conclusion (42 U.S.C. 6834(a)(3)(D)(i)(II)). ECPA as amended by EISA further directs that such an adjustment does not apply to GSA (42 U.S.C. 6834(a)(3)(D)(i)(II)).

Today’s proposed rule on fossil fuel-generated energy consumption reduction proposes to amend certain portions of 10 CFR parts 433 and 435, the regulations governing energy efficiency in Federal buildings. Additionally, DOE published a proposed rule on sustainable design standards for new Federal buildings on May 28, 2010 (75 FR 29933), which also proposes to amend certain portions of 10 CFR parts 433 and 435. DOE has already addressed some elements of today’s proposed rule in the sustainable design proposed rule. Specifically, overlapping elements of both proposed rules are the definitions of “new Federal building” and “major renovation.” The proposed regulatory text in today’s document would amend the current regulatory text, without consideration of amendments that may result from the sustainable design rulemaking. If and when these two rulemakings are finalized, DOE will coordinate the final regulatory text between the two rulemakings.

In addition, there are a number of statutory provisions, regulations,

Executive Orders, and memorandums of understanding that govern the construction of new Federal buildings or major renovations to Federal buildings. These include, but are not limited to, Executive Order 13514 (74 FR 52117); sections 323, 433, 434, and 523 of the Energy Independence and Security Act 2007 (Pub. L. 110–140); Executive Order 13423 (72 FR 3919); the Guiding Principles for Federal Leadership in High Performance and Sustainable Buildings originally adopted in the Federal Leadership in High Performance and Sustainable Buildings MOU; section 109 of the Energy Policy Act of 2005 (Pub. L. 109–58); and 10 CFR parts 433 and 435. If made final, the proposed rule would not supersede other applicable legal requirements for new Federal buildings or major renovations to Federal buildings.

II. Discussion of Proposed Rule

A. Overview

The proposed rule would establish revised Federal building energy efficiency performance standards for achieving the reductions in fossil fuel-generated energy consumption as listed in ECPA as amended by EISA (42 U.S.C. 6834(a)(3)(D)(i)(I)). The proposed rule would also clarify which building types are covered by the standards and which building types are excluded. The proposed rule establishes a methodology for compliance, including calculation of the maximum allowable fossil fuel-generated energy consumption based on building type, and how fossil fuel consumption resulting from electricity usage should be considered. Today’s proposed rule would also establish procedures for agencies to petition DOE for downward adjustment of the applicable percentage reduction requirement.

B. Scope of Proposed Rule

Section 305(a)(3) of ECPA as amended directs DOE to establish regulations that require fossil fuel-generated energy consumption reductions be applied to a subset of new Federal buildings and Federal buildings undergoing major renovation. (42 U.S.C. 6834(a)(3)(D)(i)(I)) A building is in the subset of new Federal buildings and Federal buildings undergoing major renovations if the building is:

- A public building as defined in 40 U.S.C. 3301,¹ for which the

¹ Under 40 U.S.C. 3301(5) “public building” is a building, whether for single or multitenant occupancy, and its grounds, approaches, and appurtenances, which is generally suitable for use as office or storage space or both by one or more

Administrator of General Services is required to transmit a prospectus to Congress under U.S.C. Title 40, section 3307, or

- A building and major renovation for which the construction project cost is at least \$2,500,000 (in 2007 dollars, adjusted for inflation using U.S. Department of Labor Producer Price Indexes).

DOE notes that the definition of “Federal building” was changed in statute, and DOE is addressing that definition and the definition of “new Federal building” in a separate rulemaking. (42 U.S.C. 6832(6)) The statute now defines “Federal building” to mean any building to be constructed by, or for the use of, any Federal agency. In the separate rulemaking DOE is proposing that the term include buildings built for the purpose of being leased by a Federal agency, and privatized military housing.

For the purpose of this rulemaking, DOE would consider public buildings to include buildings leased by a Federal agency. DOE recognizes, however, that a Federal agency may not have control over the design of a renovation of a leased building in which the agency is a tenant. For the purpose of this rulemaking, DOE considers major renovations to be limited to those renovations for which a Federal agency has significant control over the renovation design.

Additionally, DOE would consider construction project costs to be those costs for which the agency currently has

Federal agencies or mixed-ownership Government corporations.

“Public building” includes Federal office buildings, post offices, customhouses, courthouses, appraisers stores, border inspection facilities, warehouses, record centers, relocation facilities, telecommuting centers, similar Federal facilities, and any other buildings or construction projects the inclusion of which the President considers to be justified in the public interest.

The definition does not include a building or construction project that is on the public domain (including that reserved for national forests and other purposes); that is on property of the Government in foreign countries; that is on Indian and native Eskimo property held in trust by the Government; that is on land used in connection with Federal programs for agricultural, recreational, and conservation purposes, including research in connection with the programs; that is on or used in connection with river, harbor, flood control, reclamation or power projects, for chemical manufacturing or development projects, or for nuclear production, research, or development projects; that is on or used in connection with housing and residential projects; that is on military installations (including any fort, camp, post, naval training station, airfield, proving ground, military supply depot, military school, or any similar facility of the Department of Defense); that is on installations of the Department of Veterans Affairs used for hospital or domiciliary purposes; or the exclusion of which the President considers to be justified in the public interest.

funding. That is, the \$2,500,000 threshold would not include renovation activities that potentially could occur in future fiscal years. Generally, construction project costs include design, permitting, construction (materials and labor), and commissioning costs. Land and legal costs would generally not be included. DOE requests comment on this definition of construction costs.

DOE is proposing that Federal agencies would be required to comply with the final rule starting one year from the date of the final rule. As proposed, covered buildings for which design for construction begins on or after that effective date must meet the requirements established in this rule. The one year period would provide Federal agencies sufficient time to revise new building designs prior to the start of construction and would be consistent with that the lead time provided for the energy efficiency performance standards for the construction of all new Federal buildings.

C. Fiscal Year Percentage Reductions

Section 305 of ECPA as amended by EISA mandates that buildings subject to this proposed rule be designed to reduce fossil fuel-generated energy consumption by 55 percent beginning in fiscal year 2010, 65 percent beginning in fiscal year 2015, 80 percent beginning in fiscal year 2020, 90 percent beginning in fiscal year 2025, and 100 percent beginning in fiscal year 2030 (42 U.S.C. 6834(a)(3)(D)(i)(I)). DOE interprets this table in the statute to mean that any building whose design for construction begins in the fiscal year specified in the statute must be designed to achieve the fossil fuel-generated energy consumption reductions for that fiscal year. DOE welcomes comments on this interpretation. DOE interprets the fiscal years listed in the statute as spans of years for which the fossil fuel-generated energy consumption reductions would apply. For instance, the applicable percentage reduction for fiscal year 2010 would apply for the time span of fiscal year 2010 through fiscal year 2014. The applicable percentage reduction for fiscal year 2015 would apply for the time span of fiscal year 2015 through fiscal year 2019, and so on. DOE welcomes comments on this interpretation. Congress directed DOE to establish a rule addressing these fossil fuel-generated energy consumption reductions beginning in fiscal year 2010. DOE believes that the fossil fuel-generated energy consumption reductions do not apply to Federal agencies until the regulations

implementing the reductions are finalized. Today's proposed rule would apply to buildings for which design for construction begins at least one year after the final rule is issued.

D. Methodology To Determine Compliance

Section 305 of ECPA as amended by EISA in part requires that the buildings that are the subject of today's proposed rule be designed so that the fossil fuel-generated energy consumption of the buildings is reduced, as compared with such energy consumption by a similar building in fiscal year 2003 (as measured by Commercial Buildings Energy Consumption Survey or Residential Energy Consumption Survey data from the Energy Information Agency), by the percentages specified in Section 305 of ECPA. (42 U.S.C. 6834(a)(3)(D)(i)(I)).

Determine Baseline Fossil Fuel-Generated Energy Consumption of Similar Building

To determine whether a building meets the numeric fossil fuel reduction requirements specified by ECPA as amended by EISA, it is necessary to establish a baseline against which the reductions can be measured. For purposes of this proposed rulemaking, the statute establishes the baseline to be energy consumption data from Commercial Buildings Energy Consumption Survey (CBECS) for commercial buildings and Residential Buildings Energy Consumption Survey (RECS) for residential buildings. The CBECS and RECS data, which can be found at <http://www.eia.doe.gov/emeu/cbecs/contents.html> and at <http://www.eia.doe.gov/emeu/recs/contents.html>, are based on actual reported energy use over a large sample of buildings, normalized for size to thousands of British thermal units per square foot of floor space (kBtu/ft²).

ECPA as amended by EISA requires that the buildings subject to this proposed rule be designed so that the fossil fuel-generated energy consumption of the buildings is reduced as compared with energy consumption data of a similar building in fiscal year 2003 as measured by CBECS or RECS (42 U.S.C. 6834(a)(3)(D)(i)(I)). The limited number of buildings surveyed by CBECS and RECS data does not always allow for a direct estimate of building energy use by climate zone and building type because there are only a few surveyed buildings that fit into some building type/climate zone groups. DOE believes, however, that a climate adjustment is necessary to provide reasonable baselines. Therefore,

DOE is developing fossil fuel-generated energy requirements based on building type using CBECS or RECS data, and then applying a climate adjustment using the climate zones defined in the baseline energy efficiency standards at 10 CFR parts 433 and 435. This ensures that new Federal buildings will have to achieve reductions commensurate to a baseline appropriate for their respective climate zone, rather than to a national average that does not account for the impacts of the local climate on the energy use of a specific building. DOE solicits comment on the best technique for calculating the climate adjustment for the different building types.

Note that ECPA as amended by EISA makes no distinction between fossil fuels such as natural gas, petroleum, and coal for purposes of the required fossil fuel-generated reductions addressed in today's rule. DOE recognizes that some fossil fuels have higher CO₂ emission factors than other fossil fuels, with coal being the highest and natural gas being the lowest. While the statute does not specifically direct DOE to consider variation in fossil fuels for purposes of this rulemaking, it does not prohibit DOE from doing so. With this in mind, DOE seeks public comment on whether all fossil fuels should be treated equally or whether each should be treated differently based on CO₂ emission factors or some other factor.

Commercial Buildings Baseline—CBECS

ECPA as amended by EISA requires that the fossil fuel-generated energy consumption of new Federal buildings and Federal buildings undergoing major renovations be compared to that of similar buildings in fiscal year 2003 as measured by CBECS or RECS data (42 U.S.C. 6834(a)(3)(D)(i)(I)). The most recent available CBECS data is from a CBECS survey that was conducted in 2003.

As discussed in the previous section, for purposes of establishing a baseline, DOE is developing a baseline based on building type, as defined by CBECS, with a climate adjustment as discussed previously. In the CBECS data, Column G of the following table, http://www.eia.doe.gov/emeu/cbecs/cbecs2003/detailed_tables_2003/2003set9/2003excel/c3.xls, lists the energy use per square foot of various groups of buildings. Note that in CBECS documents, the phrases *building type* and *principal building activity* are used interchangeably. For the sake of consistency, this document only uses the phrase *building type*.

It should be noted that DOE has commissioned an analysis of the 2003

CBECS data by building type and climate zone, and the results may be found in the report *Methodology for Modeling Building Energy Performance Across the Commercial Sector* by the National Renewable Energy Laboratory (NREL/TP-550-41956 2008) at http://apps1.eere.energy.gov/buildings/publications/pdfs/commercial_initiative/energy_use_intensity_targets.pdf. Examination of Table 4 in the analysis DOE commissioned indicates the insufficient sample size of the CBECS data when both building type and climate zone are used to characterize building energy consumption. DOE's analysis produced often erratic and large variation in kBtu/ft² by building type across the different climate zones and even across similar climate zones, indicating an insufficient sample size. For this reason, DOE is performing additional analysis and processing of the CBECS data with the goal of producing CBECS-based requirements by building type and climate zone, with the climate zones as defined in the baseline standard for 10 CFR part 433 (ANSI/ASHRAE/IESNA Standard 90.1-2004).

One issue that arises with the use of this CBECS data is what to do with buildings that are split into multiple building types. It is quite common to find buildings that are a combination of warehouse and office, or warehouse and retail, or education and office, or laboratory and office, or some other combination of building types. Today's proposed rule will offer agencies the option to perform a building area-weighted average in order to determine the appropriate baseline level of fossil fuel-generated energy consumption. This process is described in 10 CFR 433.4(e) of the proposed rule.

CBECS does not provide data on total fossil fuel-generated energy consumption in buildings. However, fossil fuel-generated energy consumption can be calculated from CBECS data by using the following equation:

Fossil fuel-generated energy consumption = Direct consumption of fossil fuels in the building plus the amount of electrical energy consumption that is generated from fossil fuels

The 2003 CBECS lists direct consumption of fossil fuels in Table C1 (http://www.eia.doe.gov/emeu/cbecs/cbecs2003/detailed_tables_2003/2003set9/2003excel/c1.xls) in columns labeled natural gas and fuel oil. The 2003 CBECS also identifies both the primary electrical energy, which is the

total energy used to generate and transmit electricity to a building, and the energy content of the electricity consumed in the building. In CBECS energy consumption data, the primary electrical energy required to generate and transmit electricity to the point of use in a building is roughly three times the energy content of the electricity itself. The fraction of electricity generated from fossil fuels on a nationwide basis, referred to in this document as the fossil fuel generation ratio, is calculated from data in Table 2.1 of the Energy Information Administration (EIA) 2008 Electric Power Annual Report (<http://www.eia.doe.gov/cneaf/electricity/epa/epat2p1.html>) by summing the electric generation from coal, petroleum, natural gas, and other gases (derived from fossil fuels) and then dividing by the total electric generation. The fossil fuel generation ratio changes each year. Because ECPA as amended by EISA requires that the fossil fuel-generated energy consumption in new buildings and those undergoing major renovations be compared to that of similar buildings in fiscal year 2003, the 2003 fossil fuel generation ratio must be used in order to calculate the baseline fossil fuel-generated energy consumption levels. For 2003, the fossil fuel generation ratio was 0.71, meaning that about 71% of all electricity in the United States is generated from fossil fuels.

The approach taken in today's rulemaking to estimate the fossil fuel consumption associated with electricity consumption applies the national average contribution of fossil fuel to electricity generation. This approach would result in reductions in electricity consumption being treated the same across all geographic areas, and would not reflect regional variations in the contribution of fossil fuels to electricity generation. DOE is considering a regional approach to establishing the average fossil fuel fraction associated with building energy use. Prior to reaching a conclusion regarding the use of national or regional averages of fossil fuel inputs to the electric sector, DOE will evaluate both approaches and both average and marginal factors to determine their likely effects on agency decision-making and their ability to provide an accurate indication of the likely impacts of reductions in Federal agency electricity use on the use of fossil fuels in the electric sector. For example, the use of national average fossil fuel inputs to electric sector (rather than regional averages) may provide a better indication of the actual fossil fuel reductions likely to result

from reductions in electricity use. Reductions in future electricity demand are likely to cause electric utilities to reduce the power supplied by those electricity generation units or sources that have the highest marginal costs. Over both the short and long run, the types of power generation that have the highest marginal costs are more likely to be fossil fuel units than those powered by nuclear, hydropower or other renewable energy sources. This is likely to be true in all regions of the country, regardless of their current or projected reliance on fossil fuels to generate electricity. Regional marginal fossil fuel reduction factors may also be appropriate. DOE invites comments on whether it should use a national or regional approach and average or marginal factors to estimate the fossil fuel consumption associated with electricity consumption, taking into consideration the potential implications on agency decision-making and actual fossil fuel use.

The fossil fuel-generated energy consumption baseline column in Table 1 below is calculated directly from Table C1 in the 2003 CBECS. For each building type, the primary electrical energy is multiplied by the fossil fuel generation ratio then added to the direct fossil fuel consumption to get the total fossil fuel-generated consumption for that particular building type. The total fossil fuel consumption is then divided by the total floorspace for that building type to get the fossil fuel-generated energy consumption, as reported in Table 1 below. DOE is proposing building type definitions based largely on the CBECS glossary, with some minimal modifications for regulatory clarity. DOE requests comment on the building type definitions.

The baselines provided in Table 1 do not currently reflect any adjustment for climate-related variations in building energy use. As discussed elsewhere in this proposed rule, DOE believes a climate adjustment is necessary to provide reasonable baselines, and DOE is seeking comment on this issue. In a final rule, DOE intends to update the values provided in Table 1 for climate.

Residential Buildings Baseline—RECS

ECPA as amended by EISA requires that the fossil fuel-generated energy consumption of new Federal buildings and Federal buildings undergoing major renovations be compared to that of similar buildings in fiscal year 2003 as measured by CBECS or RECS data (42 U.S.C. 6834(a)(3)(D)(i)(I)). Residential Energy Consumption Surveys (RECS) were conducted in 2001 and 2005; there is no data for 2003. Because the 2005

RECS data is the most recently available data at the time of this proposed rulemaking, DOE expects to use the 2005 RECS data as a baseline.

As with the CBECS data for commercial buildings, the limited number of buildings surveyed by RECS data does not always allow for a direct calculation of building energy use by climate zone and building type without additional analysis. DOE believes, however, that a climate adjustment is necessary to provide more reasonable baselines. DOE, therefore, proposes to establish fossil fuel-generated energy requirements based on building type using RECS data, and then apply a climate adjustment using the climate zones defined in the baseline energy efficiency standard at 10 CFR part 435 (the 2004 IECC). This ensures that new Federal buildings will have to achieve reductions commensurate to a baseline appropriate for their respective climate zone, rather than to a national average baseline that is either too cold or too warm for their particular needs. DOE solicits comment on the best technique for calculating the climate adjustment for the different building types.

The 2005 RECS lists direct consumption of fossil fuels by households in Table US9 available at http://www.eia.doe.gov/emeu/recs/recs2005/hc2005_tables/c&e/excel/tableus9.xls in columns labeled natural gas, fuel oil, kerosene, and LPG. To calculate the total fossil fuel-generated energy consumption per household for each type of housing unit, the direct fossil fuel consumption per household and fossil fuel consumption for electricity consumption per household are summed, using the same factors to determine the fossil fuel fraction of residential electricity consumption that was used for commercial buildings. The total fossil fuel-generated energy consumption per household is then divided by the average floorspace for each type of housing unit. The average floor space for each type of housing unit can be found at <http://www.eia.doe.gov/emeu/recs/recs2005/c&e/summary/excel/tableus1part1.xls>. This calculation produces the fossil fuel use per square foot for each type of housing unit. The results can be found in the baseline column of Table 2 below. DOE is proposing building type definitions

based largely on the RECS glossary, with some minimal modifications for regulatory clarity. For example, the 2005 RECS data includes values for “manufactured homes” although the RECS glossary does not define “manufactured homes” but does define “mobile home.” DOE requests comment on the building type definitions.

The baselines provided in Table 2 do not currently reflect any adjustment for climate-related variations in building energy use. As discussed elsewhere in this proposed rule, DOE believes a climate adjustment is necessary to provide reasonable baselines, and DOE is seeking comment on this issue. In a final rule, DOE intends to update the values provided in Table 2 for climate.

When using Table 2, it is important to note a shortcoming of RECS data for use in performance standards for Federal buildings. The shortcoming is that RECS data is collected on a per household basis and does not include energy use in common areas. As a result, the value for fossil fuel-generated energy consumption per square foot of floorspace shown in Table 2 only accounts for the non-common areas of these buildings. DOE considered accounting for common area energy use in the requirements, but RECS does not collect that data. To resolve this issue, DOE proposes applying the RECS-derived fossil fuel requirements to all applicable floorspace, including common and non-common areas. The benefits of this approach are that it is relatively simple and will not make it more difficult for building designers to show compliance. Because common areas account for a small fraction of floorspace, the effect on the requirement will be minimal. Also, common areas often have a lower energy intensity, so by using only non-common areas the maximum allowable fossil fuel-generated energy requirement will, if anything, be slightly higher. DOE welcomes comments on this approach or other specific approaches that could be used to develop the RECS-derived requirements.

Calculation of Maximum Allowable Fossil Fuel-Generated Energy Consumption

Once the baseline fossil fuel-generated energy consumption from the

2003 CBECS and 2005 RECS has been determined, the consumption reduction requirements as specified in ECPA as amended by EISA should be calculated. Again, although the baselines provided in Tables 1 and 2 do not currently reflect any adjustment for climate-related variations in building energy use, DOE is developing fossil fuel-generated energy requirements based on building type using CBECS or RECS data, and then applying a climate adjustment. In a final rule, DOE intends to update the values provided in Tables 1 and 2 for climate.

The requirements derived from CBECS, which apply to commercial buildings, are shown in Table 1. The consumption reduction requirements derived from RECS, which apply to both multi-family high-rise residential buildings and low-rise residential buildings, are found in Table 2. In this rulemaking DOE is proposing a revised definition of “Multi-family high-rise residential building,” largely based on the definition at 10 CFR 434.201, although the proposed definition clarifies that multi-family high-rise residential buildings are designed to be four or more stories above grade.

As discussed above, Tables 1 and 2 show data only at the national level, with national average values used for the fossil fuel generation ratio of 0.71. As discussed elsewhere in this rule, DOE is considering and invites comments on whether it should use a national or regional approach and average or marginal factors to estimate the fossil fuel consumption associated with electricity consumption.

For purposes of simplification, values in these tables have been truncated to the nearest kBtu/ft². In today’s notice, the fossil fuel-generated energy consumption percentage reductions are presented as maximum allowable fossil fuel-generated energy consumption levels. Because the figures are premised on the proposed baseline values, the percentage reductions equate to the absolute values which are presented as the maximum allowable values. For ease of agency interpretation, the maximum allowable approach was used in today’s notice.

TABLE 1—2003 CBECS FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BASELINE AND MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING TYPE AND FISCAL YEAR (FY), kBtu/ft²

| Building type | Baseline (kBtu/ft ²) | FY 2012–2014 | FY 2015–2019 | FY 2020–2024 | FY 2025–2029 | FY 2030 and beyond |
|--------------------------------|----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|--|
| | | 55% reduction (kBtu/ft ²) | 65% reduction (kBtu/ft ²) | 80% reduction (kBtu/ft ²) | 90% reduction (kBtu/ft ²) | 100% reduction (kBtu/ft ²) |
| Education | 126 | 57 | 44 | 25 | 13 | 0 |
| Food Sales | 387 | 174 | 135 | 77 | 39 | 0 |
| Food Service | 404 | 182 | 141 | 81 | 40 | 0 |
| Health Care (Inpatient) | 313 | 141 | 109 | 63 | 31 | 0 |
| Health Care (Outpatient) | 148 | 67 | 52 | 30 | 15 | 0 |
| Lodging | 148 | 67 | 52 | 30 | 15 | 0 |
| Retail (Other Than Mall) | 126 | 57 | 44 | 25 | 13 | 0 |
| Office | 160 | 72 | 56 | 32 | 16 | 0 |
| Public Assembly | 125 | 56 | 44 | 25 | 12 | 0 |
| Public Order and Safety | 146 | 66 | 51 | 29 | 15 | 0 |
| Religious Worship | 62 | 28 | 22 | 12 | 6 | 0 |
| Service | 113 | 51 | 40 | 23 | 11 | 0 |
| Warehouse and Storage | 66 | 30 | 23 | 13 | 7 | 0 |

TABLE 2—2005 RECS FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BASELINE AND MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY TYPE OF HIGH-RISE OR LOW-RISE HOUSING UNIT, kBtu/ft²

| Building type | Baseline (kBtu/ft ²) | FY 2012–2014 | FY 2015–2019 | FY 2020–2024 | FY 2025–2029 | FY 2030 and beyond |
|--|----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|--|
| | | 55% reduction (kBtu/ft ²) | 65% reduction (kBtu/ft ²) | 80% reduction (kBtu/ft ²) | 90% reduction (kBtu/ft ²) | 100% reduction (kBtu/ft ²) |
| Single-Family Detached | 59 | 27 | 21 | 12 | 6 | 0 |
| Single-Family Attached | 66 | 30 | 23 | 13 | 7 | 0 |
| Multi-Family in 2–4 Unit Buildings | 105 | 47 | 37 | 21 | 11 | 0 |
| Multi-Family in 5 or More Unit Buildings | 94 | 42 | 33 | 19 | 9 | 0 |
| Manufactured Homes | 115 | 52 | 40 | 23 | 12 | 0 |

DOE recognizes that the required reductions identified in the above tables for the years preceding FY 2030 may change based on how climate and fossil fuels are considered and characterized. However, the FY 2030 requirement for buildings to be designed such that the fossil fuel-generated energy consumption is zero would remain unchanged.

Although ECPA as amended by EISA requires that new Federal buildings and Federal buildings undergoing major renovations be designed so that fossil fuel-generated energy consumption of the buildings is reduced as compared with such energy consumption by a similar building in fiscal year 2003 (as measured by CBECS and RECS), there are some building types for which no amount of processing of CBECS and RECS data will yield an appropriate baseline for comparison. Examples might include industrialized or research facilities. For purpose of determining the Maximum Allowable Fossil Fuel Energy Consumption for these buildings not addressed by CBECS or RECS, DOE proposes to use the ASHRAE's Performance Rating Method to

determine the baseline energy consumption for a new Federal commercial or multi-family high-rise residential building, and the IECC's Simulated Performance Alternative to determine the baseline energy consumption for a new Federal low-rise residential building. DOE welcomes input on this approach.

Calculation of Proposed Building Fossil Fuel-Generated Energy Consumption

To determine compliance, DOE is proposing that the fossil fuel-generated energy consumption of the proposed new Federal building or Federal building undergoing major renovation should be estimated using the Performance Rating Method found in Appendix G of ANSI/ASHRAE/IESNA Standard 90.1–2004 for commercial and multi-family high-rise residential buildings, and the ICC International Energy Conservation Code 2004 Supplement for low-rise residential buildings. These are the same methods already prescribed at 10 CFR parts 433 and 435, respectively. Because of the complexity involved in estimating fossil fuel-generated energy consumption, this

compliance requirement effectively requires the use of a whole building simulation tool. Whole building simulations are already performed today for most medium- and large-sized buildings to accurately estimate loads for purposes of sizing HVAC equipment for evaluating buildings under voluntary industry building codes. The outputs from these tools typically include site energy usage for both electricity and fossil fuel.

To compare the estimated fossil fuel-generated energy consumption from the whole-building simulation tool to the maximum allowable fossil fuel-generated energy consumption under the statute, the designer should first calculate the primary electrical energy by multiplying the site electrical energy (from the whole building simulation), including receptacle and process loads, by the electricity source energy factor. The designer then calculates the fossil fuel-generated electrical consumption by multiplying the primary electrical energy by the fossil fuel-generation ratio. Finally, the designer must then sum up the fossil fuel-generated electrical consumption and any non-

electrical fossil fuels directly used in the proposed building (such as gas furnaces, gas cooking stoves, gas water heaters, *etc.*). The sum should be less than or equal to the required fossil fuel-generated energy consumption value for the appropriate building type.

The electricity source energy factor is the ratio of primary electrical energy consumed to generate and deliver energy to a site to the electrical energy consumed on site. DOE is proposing that the electricity source energy factor would be calculated by dividing the average utility delivery ratio in Table 6.2.4 of the DOE Building Energy Data Book (http://buildingsdatabook.eren.doe.gov/docs/xls_pdf/6.2.4.xls) by 3412 to convert the value from Btu/kWh to kWh/kWh. The fossil fuel generation ratio would be calculated using the EIA's latest Electric Power Annual report by summing the electric generation from coal, petroleum, natural gas, and other gases (derived from fossil fuels) and then dividing by the total electric generation.

DOE notes that the simulation analysis requirement may be burdensome for designers of some buildings, particularly small buildings. DOE also acknowledges that the Advanced Energy Design Guides (AEDGs) have been completed for a few building types, including the most significant commercial building types and sizes, but the AEDGs are not designed to achieve the reduction levels necessary under this rule. DOE welcomes comments on alternatives to a whole building simulation to demonstrate compliance of these buildings with the requirements of this proposed rulemaking. DOE also welcomes comments on the calculations methods discussed in this section.

Plug and Process Energy Consumption

EPACT 2005 as amended by EISA requires that building be designed so that the fossil fuel-generated energy consumption of the buildings is reduced as compared with such energy consumption by a similar building as measured by CBECS and RECS. All building energy consumption, including plug and process energy consumption, is included in baseline CBECS and RECS data, and thus is also factored into the maximum allowable fossil fuel-generated energy consumption. Therefore, it is necessary that plug and process loads also be included in the fossil fuel-generated energy consumption of the new Federal building or Federal building undergoing major renovations. This is consistent with Table G3.1.12 in Appendix G, Performance Rating Method, ASHRAE

Standard 90.1–2004. DOE acknowledges the difficulty of estimating plug and process loads and that their inclusion may make it more difficult to achieve the mandated fossil fuel-generated energy consumption reductions. DOE welcomes comments on how the proposed rule can be designed such that the assumptions used in the whole building simulations accurately reflect, to the best degree possible, the final building design and the operation of the building, including plug and process loads.

Purchase of Offsite Renewable Energy

In order to meet the maximum allowable fossil fuel-generated energy consumption requirements mandated by ECPA as amended by EISA, fossil fuel-generated energy consumption could be offset with use of energy created from other sources, including renewable energy sources. DOE also recognizes there may be physical limitations to the amount of on-site renewable electricity that can be produced, and it may be more affordable in some cases for an agency to purchase electricity from centralized renewable energy-generation facilities. As an example, ASHRAE Standard 189.1–2009, “The Standard for High-Performance Green Buildings,” has an on-site renewable energy requirement, but allows the use of Renewable Energy Certificates as an alternative to meet the requirement.

DOE is concerned however, that purchase of renewable energy-generated electricity via Renewable Energy Certificates or direct Power Purchase Agreements may simply reduce the amount of renewable energy available for purchase by other entities within the U.S. and may not necessarily lead to an overall decrease in domestic fossil fuel-generated energy consumption. In addition, unlike Power Purchase Agreements, the purchase of Renewable Energy Certificates does not involve a long-term binding agreement and can readily be cancelled. It should also be noted that the use of Renewable Energy Certificates is being phased out by January 2012, as a way to meet the renewable energy consumption levels established under section 203 of EPACT 2005 and Executive Order 13423 (*see* “Renewable Energy Requirement Guidance for EPACT 2005 and Executive Order 13423,” available at: http://www1.eere.energy.gov/femp/pdfs/epact05_fedrenewenergyguid.pdf).

DOE is leaning toward allowing Power Purchase Agreements with a long-term contract to count toward meeting the fossil fuel-generated energy consumption reduction requirements, but not allowing Renewable Energy

Certificates. Under this approach, agencies would be allowed to subtract the annual electricity generated by the renewable energy-generation facility from the building's annual site electrical energy consumption. The building designer would use this quantity, the net site electrical energy consumption, when calculating the building's fossil fuel-generated energy consumption. In effect, the Power Purchase Agreements would help agencies meet the fossil fuel consumption requirements. DOE invites comments on how Renewable Energy Certificates and Power Purchase Agreements should be addressed in the context of this rulemaking. DOE also invites comments on the proposed approach with respect to Power Purchase Agreements.

Potential Impact on Onsite Electrical Generation From Natural Gas

DOE is interested in the effect of fossil fuel-generated energy consumption reduction requirements on distributed energy technologies that provide onsite electrical generation from natural gas such as in power plants and combined heat and power (CHP) systems. At power plants and in CHP systems, natural gas is used to generate both heat and electricity. A building with a CHP system could potentially be an all-gas building in terms of utility purchases and would therefore be required to reduce natural gas consumption in accordance with the fossil fuel-generated energy consumption reduction requirements. DOE's intent is to ensure the rule does not penalize or discourage the use of on-site CHP systems, and invites comments how appropriate credit may be given for CHP systems through the compliance determination methodology.

E. Cost Analysis

Given the significant reductions in fossil fuel-generated energy consumption that would be required in today's proposed rulemaking, one obvious question is how much will compliance with this proposed rule impact the cost of new Federal construction and major renovations. The answer to that question depends both on the building type and type of housing unit being constructed and the level of fossil fuel-generated energy consumption reduction that is required. DOE commissioned a study by Pacific Northwest National Laboratory in 2008 to look at the incremental costs of high performance buildings. Cost data for high performance buildings is fairly rare and many times the costs for achieving high levels of energy efficiency are intermingled with the costs to achieve

more sustainable design. That report entitled, "Literature Review of Data on the Incremental Costs to Design and Build Low-Energy Buildings (Hunt, WD, 2008, PNNL-17502 and available at http://www.pnl.gov/main/publications/external/technical_reports/PNNL-17502.pdf) came to the following key findings as noted in the summary of the document:

Key findings of this literature review are as follows:

1. Objectively-developed and verifiable data on the cost premium for low-energy (high efficiency) buildings are very limited. Most of the literature focused on green or sustainable buildings, not on low-energy buildings.
2. In cases where energy efficiency cost data were available, the cost premiums ranged from 1% to 7%. In most cases, the cost premium was less than 4%.
3. Technology solutions are available right now to achieve savings on the order of 30% and more over ASHRAE Standard 90.1-2004; however, cost-effectiveness of these technology solutions is often not addressed.
4. Independent surveys administered to assess the perceptions of building owners and designers regarding the costs to build and operate green/energy-efficient buildings, and the willingness of owners/developers to invest in green/energy-efficient buildings, reveal some interesting common threads.

i. There is a perception that energy-efficient/green buildings cost significantly more to design (starting at a 5% premium) and represent a key barrier with decision makers.

ii. There seems to be a potential willingness (as implied or measured through survey responses) to build more energy-efficient buildings for cost premiums below 5%.

In response to the third key finding listed in the report, DOE began calculating cost impacts for their work associated with AEDGs. Cost impact data are available in the technical support document (TSD) of one published ASHRAE AEDG for small warehouses that are 30% better than Standard 90.1-2004 and four TSDs prepared by DOE for support of future AEDGs that will achieve 50% savings over Standard 90.1-2004. The four TSDs are for medium offices, roadside lodging, general retail, and grocery stores. DOE expects to develop six additional TSDs for small offices, large offices, quick service restaurants, large hospitals, university dormitories, and K-12 schools in FY10. These additional TSDs were not available at the time this notice was prepared.

The available TSDs may be found at: Small Warehouse (30% savings)—

http://www.pnl.gov/main/publications/external/technical_reports/PNNL-17056.pdf. General Merchandise (50% savings)—<http://www.nrel.gov/docs/fy09osti/46100.pdf>. Grocery Stores (50% savings)—<http://www.nrel.gov/docs/fy09osti/46101.pdf>. Highway Lodging Buildings (50% savings)—http://www.pnl.gov/main/publications/external/technical_reports/PNNL-18773.pdf. Medium Office (50% savings)—http://www.pnl.gov/main/publications/external/technical_reports/PNNL-19004.pdf.

Results from the cost analyses in three of these TSDs—small warehouse, highway lodging, and medium office—are shown below in Table 3. Ranges in the results are a function of climate zone, with buildings in some climates zones costing more or generating less energy savings. Multiple HVAC systems were evaluated for the 50% medium office—a more efficient but more expensive radiant system and a more standard variable air volume (VAV) system. It should be noted that all of the buildings analyzed for the TSDs did have increased first costs, but that the energy savings provided relatively good payback periods.

TABLE 3—COST EFFECTIVENESS ANALYSIS OF HIGHLY ENERGY EFFICIENT BUILDINGS

| TSD | Building square footage | Incremental cost (\$ per ft ²) | Incremental cost (percentage increase) | Simple payback on energy savings (years) |
|---------------------|------------------------------|--|--|--|
| Warehouse | 50,000 ft ² | 1.88 to 3.56 | 2.6% to 7% | 6.0 to 13.5. |
| Highway Lodging ... | 43,000 ft ² | 7.58 to 10.85 | 8.4% to 8.7% | 9.6 to 15.9. |
| Medium Office | 53,600 ft ² | 5.47 to 9.03 (Radiant) 2.37 to 4.22 (VAV). | 5.4% to 7.0% (Radiant) 2.7% to 3.9% (VAV). | 5.6 to 11.1 (Radiant) 3.3 to 6.2 (VAV). |

Consideration of the graduated levels of fossil fuel-generated energy consumption reduction listed in the statute (55%, 65%, 80%, 90%, and 100%), coupled with the fact that a percentage reduction is not directly comparable to a 30% or 50% savings over ASHRAE Standard 90.1-2004, makes it hard to determine what level of savings is associated with the 1% to 7% cost premiums cited in the PNNL study ("Literature Review of Data on the

Incremental Costs to Design and Build Low-Energy Buildings," Hunt, WD, 2008, PNNL-17502). Converting both the requirements of this proposed rulemaking and the simulated performance of buildings built to 30% better than ASHRAE Standard 90.1-2004 to a common Energy Use Intensity basis provides a better method of comparison. Also note that the comparison must be made on a similar energy basis. Today's proposed

rulemaking applies to fossil fuel-generated energy consumption, which is close to source energy, while results from the TSDs are typically expressed in site energy.

Table 4 shows the comparison of the fossil fuel-generated energy consumption reductions proposed in this rulemaking to the fossil fuel reductions achieved in the simulations associated with two of the TSDs, the medium office and highway lodging.

TABLE 4—FOSSIL FUEL-GENERATED ENERGY CONSUMPTION PROPOSED IN TODAY'S RULEMAKING AND CALCULATED IN SELECTED AEDGS

| Building type | 55% Fossil fuel reduction from CBECs kBtu/ft ² | 65% Fossil fuel reduction from CBECs kBtu/ft ² | 80% Fossil fuel reduction from CBECs kBtu/ft ² | Fossil fuel reduction calculated in TSD kBtu/ft ² | Incremental cost (percentage increase) |
|---------------------------|---|---|---|--|--|
| Medium Office (Rad) | 72 | 56 | 32 | 49.2 | 5.4% to 7.0%. |
| Medium Office (VAV) | 72 | 56 | 32 | 63.6 | 2.7% to 3.9%. |
| Highway Lodging | 67 | 52 | 30 | 56.4 | 8.4% to 8.7%. |

Table 4 indicates that the estimated cost savings from the 50% TSDs can be used to support the fact that 55% fossil fuel-generated energy consumption reductions and perhaps even 65% fossil fuel-generated energy consumption reductions from CBECS will require cost increases of no more than 8.7%. None of the savings achieved in the 50% TSDs approach the reduction mandated at the 80% fossil fuel-generated energy consumption reduction level, so the cost estimates for that level of savings and higher levels cannot be estimated.

With respect to residential buildings, DOE does not anticipate that there will be many low-rise residential buildings that will fall under today's proposed rulemaking as most Federal low-rise residential buildings are not likely to be public buildings or buildings for which construction costs are at least \$2.5 million in 2007 dollars, which are criteria that determine whether buildings are subject to the requirements in today's proposed rule. The only low-rise residential buildings that might be considered to fall under today's proposed rule would be low-rise military barracks, and those barracks are best considered to be similar to the dormitory or lodging building types found in CBECS.

Using CBECS and RECS baselines without a climate adjustment puts buildings in colder climate zones at a cost disadvantage because the non-adjusted baseline would be lower than for one adjusted for climate. A non-adjusted baseline for colder climates would require larger, more costly fossil fuel-generated energy consumption reductions. Conversely, using CBECS and RECS baselines without a climate adjustment provides a cost advantage to buildings in warmer climate zones because the baseline would be greater than for one adjusted for climate. A non-adjusted baseline for warmer climates would require smaller, less costly fossil fuel-generated energy consumption reductions.

However, adjusting for climate in both the baseline and the required reduction level would be expected to eliminate potential regional inequity that could result from climate variation and help ensure that the fossil fuel-generated energy consumption reductions are commensurate to the climate zone. Similarly, consideration of regional variations in the fossil fuel contribution to electricity is not expected to result in substantial differences in the compliance burden for buildings across regions so long as regional variations are also reflected in the baseline buildings. If the regional values were used for both the baseline building and the required

reduction level, the burden of meeting the percentage reductions would remain roughly the same in all regions (although regions with low fossil fuel use in the electric sector might have to find more savings in non-electric end-uses).

DOE is seeking comment on a number of issues related to the cost-effectiveness of today's proposed rule, especially any construction cost increases for buildings Federal agencies are in the process of designing or have already built. DOE is seeking comment on these cost impacts.

F. Agency Petitions for Adjustment to the Percentage Reduction Requirement

ECPA as amended by EISA permits DOE upon petition by an agency subject to the statutory requirements to adjust the applicable numeric fossil fuel-generated energy consumption percentage reduction requirement "downward with respect to a specific building, if the head of the agency designing the building certifies in writing that meeting such requirement would be technically impracticable in light of the agency's specified functional needs for the building" and DOE concurs with the agency's conclusion. (42 U.S.C. 6834(a)(3)(D)(i)(II)) ECPA as amended by EISA further directs that such an adjustment does not apply to GSA.

Today's action proposes that a petition for downward adjustment of the numeric requirement should include an explanation of what measures would be required to meet the fossil fuel-generated energy consumption reduction requirement, and why those measures would be technically impracticable in light of the agency's specified functional needs for the building. DOE proposes that the petition should also demonstrate that the adjustment requested by the agency represents the largest feasible reduction in fossil fuel-generated energy consumption that can reasonably be achieved. DOE welcomes comments on that proposal. Although the downward adjustment provision of ECPA as amended by EISA does not expressly include cost considerations, DOE is considering incorporating cost considerations as part of a "technically impracticable" determination. Cost would not be the sole rationale for a determination of "technically impracticable," but high costs could be part of the evaluation. (42 U.S.C. 6834(a)(3)(D)). DOE also invites comments that would help clarify what kind of technical impracticability would constitute grounds for a petition for downward adjustment.

The petition pursuant to ECPA as amended by EISA should also include a written certification statement by the head of the agency designing the building that meeting the fossil fuel-generated energy consumption reduction requirements would be technically impracticable in light of the agency's specified functional needs for that building. 42 U.S.C. 6834(D)(i)(II).

DOE notes that the statute exempts GSA from the option to petition DOE for a downward adjustment of the applicable percentage reduction requirement. However, DOE proposes that a new Federal building or a Federal building undergoing major renovations for which a Federal agency is providing substantive and significant design criteria may be the subject of a petition. Under this approach, a GSA building that is designed to meet the specifications provided by a tenant agency may be considered for a downward adjustment if a petition is submitted by the head of the tenant agency.

DOE will review petitions in a timely manner. If the petitioning agency has successfully demonstrated the need for a downward adjustment per the discussion above, DOE will concur with the agency's conclusion and notify the agency in writing. If DOE does not concur, it will forward its reasons to the petitioning agency with suggestions as to how the fossil fuel-generated energy consumption percentage reduction requirement may be achieved.

A petition for downward adjustment of the numeric reduction, including any supporting information, would be addressed to: Margo Appel, Building Technologies Program, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

G. Guidance on Measures To Reduce Fossil Fuel-Generated Energy Consumption

Building energy efficiency solutions involve advanced technologies, integrated design principles, control strategies and other tools. The appropriate solution and the effectiveness of each solution will vary based on building type, building size, and location. To successfully design a high performance building, Federal agencies must use a reputable, experienced design team. There are an increasing number of firms in all locations that have designed high performance buildings. The key to successful design is identifying firms with the requisite experience and skills, adopting an integrated design process that begins at the first phase of the building project, and providing clear

direction and quality control over the firm's work. DOE invites comment from agencies as to what additional training in this area might be helpful.

Numerous tools are available to help Federal agencies achieve the required fossil fuel reductions. DOE, in conjunction with ASHRAE, has developed a series of Advanced Energy Design Guides to achieve 30 percent reductions in energy use for several types of small buildings (small office buildings, small retail buildings, K–12 school buildings, small warehouses and self-storage buildings, highway lodging, and small hospitals and healthcare facilities). DOE and ASHRAE are working on 50 percent reduction guidelines for several building types. Additional tools and resources are available through the EERE Web site. DOE's Building Technologies Program maintains a database of high-performance buildings (available at <http://eere.buildinggreen.com>).

Other resources include: The National Institute of Building Sciences' *Whole Building Design Guide*; the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) system; ASHRAE Standard 189.1–2009, *Standard for the Design of High Performance Green Buildings Except Low-Rise Residential Buildings*; and the International Code Council's *International Green Construction Code Public Version 1.0*. DOE's Federal Energy Management Program (FEMP) Web site provides access to these and other resources and tools that can help Federal agencies improve the energy efficiency of new and existing buildings (available at <http://www1.eere.energy.gov/femp/>). DOE has also published a cool roof resource guide for Federal agencies, available at http://www1.eere.energy.gov/femp/features/cool_roof_resources.html. DOE is also developing additional guidance that provides technical and cost data related to the installation of cool roofs.

H. Post-Construction Monitoring and Reporting

ECPA as amended by EISA does not contain any explicit post-construction monitoring and reporting requirements. Federal agencies, however, are reminded of the monitoring, reporting, and benchmarking requirements in section 103 of the Energy Policy Act of 2005 (EPA 2005) and section 432 of EISA. FEMP has issued guidance for the metering requirements in section 103 of EPA 2005 (available at http://www1.eere.energy.gov/femp/pdfs/adv_metering.pdf). FEMP has also developed guidance for meeting EISA section 432 requirements (available at

http://www1.eere.energy.gov/femp/pdfs/eisa_s432_guidelines.pdf). Finally, FEMP has also issued additional guidance on EISA section 432 benchmarking (available at http://www1.eere.energy.gov/femp/pdfs/eisa_s432_guidelines.pdf).

FEMP has selected the Energy Star Portfolio Manager as the required building energy use benchmarking system for Federal agencies. Additional information on the use of Energy Star Portfolio Manager, energy management, and benchmarking in general may be found on the EPA Energy Star Web site at http://www.energystar.gov/index.cfm?c=business.bus_index.

III. Reference Resources

DOE has prepared a list of resources to help Federal agencies address the reduction of fossil fuel-generated energy consumption. The interim final rule on energy efficiency published in the **Federal Register** on December 4, 2006 (71 FR 70275) contains reference resources for energy efficiency improvement in building design. These resources come in many forms such as design guidance, case studies and in a variety of media such as printed documents or on Web sites. The resources for energy efficiency improvement will also provide guidance for fossil fuel-based energy consumption reduction.

IV. Regulatory Review

A. Review Under Executive Order 12866

Today's notice of proposed rulemaking has been determined to be a significant regulatory action under section 3(f)(1) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (October 4, 1993). Accordingly, today's action was reviewed by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small

entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of General Counsel's Web site: <http://www.gc.doe.gov>.

DOE has reviewed today's proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. Today's proposed rulemaking applies only to the fossil fuel-generated energy consumption of new Federal buildings and Federal buildings undergoing major renovation. As such, the only entities impacted by this rulemaking would be Federal agencies. DOE does not believe that there will be any impacts on small entities such as small businesses, small organizations, or small governmental jurisdictions.

On the basis of the foregoing, DOE certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

This proposed rule will impose no new information or record keeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq.*)

D. Review Under the National Environmental Policy Act

The Department prepared a draft Environmental Assessment (EA) (DOE/EA-1463) pursuant to the Council on Environmental Quality's (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR parts 1500–1508), the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and DOE's NEPA Implementing Procedures (10 CFR part 1021).

The draft EA addresses the potential incremental environmental effects attributable to the application of the proposed rules. The draft EA has been added to the docket for this rulemaking.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies

or regulations that preempt State law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined the proposed rule and determined that it would not preempt State law and would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of Government. No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct, rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) generally requires Federal agencies to examine closely the impacts of regulatory actions

on State, local, and Tribal governments. For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a) and (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA (62 FR 12820) (also available at <http://www.gc.doe.gov>). This notice of proposed rulemaking contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of \$100 million or more in any year, so these requirements under the Unfunded Mandates Reform Act do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 53 FR 8859 (March 18, 1988), that this notice of proposed rulemaking would not result in any takings which might require compensation under the Fifth Amendment to the United States Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Today's proposed rule would not have a significant adverse effect on the supply, distribution, or use of energy and, therefore, is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's notice of proposed rulemaking.

List of Subjects in 10 CFR Parts 433 and 435

Buildings and facilities, Energy conservation, Engineers, Federal buildings and facilities, Housing.

Issued in Washington, DC, on September 30, 2010.

Cathy Zoi,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE proposes to amend chapter II of title 10 of the Code of Federal Regulations as set forth below:

PART 433—ENERGY EFFICIENCY AND FOSSIL FUEL-GENERATED ENERGY CONSUMPTION REDUCTION DESIGN STANDARDS FOR NEW AND MAJOR RENOVATIONS TO FEDERAL COMMERCIAL AND MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS

1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 6831–6832, 6834–6835; 42 U.S.C. 7101 *et seq.*

2. The heading for part 433 is revised to read as set forth above.

3. Section 433.1 is revised to read as follows:

§ 433.1 Purpose and scope.

This part establishes an energy efficiency performance and maximum allowable fossil fuel-generated energy consumption standard for new Federal commercial and multi-family high-rise residential buildings, for which design for construction began on or after January 3, 2007 (except as otherwise indicated: fossil fuel-generated energy consumption requirements are applicable one year after publication of the final rule), as required by section 305(a) of the Energy Conservation and Production Act, as amended (42 U.S.C. 6834(a)). Additionally, this part establishes certain requirements applicable to major renovations of Federal commercial and multi-family high-rise residential buildings, as indicated. For renovated buildings, those requirements apply only to the portions of the building or building systems that are being renovated and to the extent that the scope of the renovation permits compliance with the applicable requirements in this part. Unaltered portions of the building or building systems are not required to comply with this part.

4. Section 433.2 is amended by adding in alphabetical order new definitions for “Direct fossil fuel consumption,” “District Energy System,” “Electricity fossil fuel-generation ratio,” “Electricity source energy factor,” “Fossil fuel,” “Fossil fuel consumption for electricity generation,” “Fossil fuel-generated energy consumption,” “Multi-family high-rise residential building,” and “Primary electrical energy consumption” to read as follows:

§ 433.2 Definitions.

* * * * *

Direct fossil fuel consumption means the total fossil fuel consumption in a building excluding fossil fuel consumption for electricity generation. This includes any fossil fuel consumption resulting from a district energy system used in a building.

District Energy System means a central energy conversion plant and transmission and distribution system that provides thermal energy to a group of buildings (heating via hot water or steam, and/or cooling via chilled water). This definition includes only thermal energy systems; central energy supply systems that provide only electricity are excluded from this definition.

* * * * *

Electricity fossil fuel-generation ratio means the fraction of national U.S. electricity generation from fossil fuel sources as provided by the Energy Information Administration Electric Power Annual report for the appropriate year.

Electricity source energy factor is the ratio of primary electrical energy consumed to generate and deliver energy to a site relative to electrical energy consumed on site. The electricity source energy factor may be calculated by dividing the average utility delivery ratio in Table 6.2.4 of the DOE Building Energy Data Book for the appropriate year by 3412 to convert the value from Btu/kWh to kWh/kWh.

* * * * *

Fossil fuel means a fuel formed in the earth from plant or animal remains. Fossil fuels include coal, oil, natural gas, kerosene, and liquefied petroleum gas (LPG).

Fossil fuel consumption for electricity generation means the primary electrical energy consumption in a building supplied from the national power grid multiplied by the electricity fossil fuel-generation ratio. Electricity generated completely from non-fossil fuel sources or from a dedicated source not connected to the national power grid is excluded from this definition.

Fossil fuel generated-energy consumption means the sum of direct fossil fuel consumption plus fossil fuel consumption for electricity generation.

* * * * *

Multi-family high-rise residential building means a residential building that contains three or more dwelling units and that is designed to be 4 or more stories above grade.

* * * * *

Primary electrical energy consumption means the total amount of energy used to generate and deliver

electrical energy to a building from the national power grid.

* * * * *

5. Section 433.4 is amended by adding new paragraphs (d), (e), and (f) to read as follows:

§ 433.4 Energy efficiency performance standard.

* * * * *

(d) All Federal agencies shall design new Federal commercial and multi-family high-rise residential buildings and major renovations to Federal commercial and multi-family high-rise residential buildings, for which design for construction began at least one year after publication of the final rule, to meet the requirements of paragraph (e) of this section if:

(1) The subject building is a public building as defined in 40 U.S.C. 3301 and for which transmittal of a prospectus to Congress is required under 40 U.S.C. 3307; or

(2) The cost of the building or major renovation is at least \$2,500,000 (in 2007 dollars, adjusted for inflation).

(e)(1) All Federal agencies shall design new Federal commercial and multi-family high-rise residential buildings and major renovations of Federal commercial and multi-family high-rise residential buildings for which design for construction began at least one year after publication of the final rule and that are classified in paragraph (d) of this section, to meet fossil fuel-generated energy consumption values equal to or lesser than the values shown in Table 1. The maximum allowable fossil fuel generated energy consumption values in Table 1 are a function of building type and fiscal year for which design for construction began.

(2) For the purpose of this paragraph (e), the following definitions apply:

(i) *Education* means buildings used for academic or technical classroom instruction, such as elementary, middle, or high schools, and classroom buildings on college or university campuses. Buildings on education campuses for which the main use is not classroom are included in the category relating to their use. For example, administration buildings are part of “Office,” dormitories are “Lodging,” and libraries are “Public Assembly.”

(ii) *Food sales* means buildings used for retail or wholesale of food. For example, grocery stores are “Food Sales.”

(iii) *Food service* means buildings used for preparation and sale of food and beverages for consumption. For example, restaurants are “Food Service.”

(iv) *Health care (inpatient)* means buildings used as diagnostic and treatment facilities for inpatient care.

(v) *Health care (outpatient)* means buildings used as diagnostic and treatment facilities for outpatient care. Medical offices are included here if they use any type of diagnostic medical equipment (if they do not, they are categorized as an office building).

(vi) *Lodging* means buildings used to offer multiple accommodations for short-term or long-term residents, including skilled nursing and other residential care buildings.

(vii) *Multi-family in 2–4 unit buildings* means a unit in a building with two to four housing units—a structure that is divided into living quarters for two, three, or four families or households in

which one household lives above or beside another. This category also includes houses originally intended for occupancy by one family (or for some other use) that have since been converted to separate dwellings for two to four families.

(viii) *Multi-family in 5 or more unit buildings* means a unit in a building with five or more housing units—a structure that contains living quarters for five or more households or families and in which one household lives above or beside another.

(ix) *Public assembly* means public or private buildings, or spaces therein, in which people gather for social or recreational activities.

(x) *Public order and safety* means buildings used for the preservation of law and order or public safety.

(xi) *Religious worship* means buildings in which people gather for religious activities, (such as chapels, churches, mosques, synagogues, and temples).

(xii) *Retail (other than mall)* means buildings used for the sale and display of goods other than food.

(xiii) *Service* means buildings in which some type of service is provided, other than food service or retail sales of goods.

(xiv) *Warehouse and storage* means buildings used to store goods, manufactured products, merchandise, raw materials, or personal belongings (such as self-storage).

TABLE 1—MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING TYPE, COMMERCIAL BUILDINGS, kBtu/ft²

| Building type | kBtu/ft ² by fiscal year for which design for construction began | | | | |
|--------------------------------|---|--------------|--------------|--------------|--------------------|
| | FY 2012–2014 | FY 2015–2019 | FY 2020–2024 | FY 2025–2029 | FY 2030 and beyond |
| Education | 57 | 44 | 25 | 13 | 0 |
| Food Sales | 174 | 135 | 77 | 39 | 0 |
| Food Service | 182 | 141 | 81 | 40 | 0 |
| Health Care (Inpatient) | 141 | 109 | 63 | 31 | 0 |
| Health Care (Outpatient) | 67 | 52 | 30 | 15 | 0 |
| Lodging | 67 | 52 | 30 | 15 | 0 |
| Retail (Other Than Mall) | 57 | 44 | 25 | 13 | 0 |
| Office | 72 | 56 | 32 | 16 | 0 |
| Public Assembly | 56 | 44 | 25 | 12 | 0 |
| Public Order and Safety | 66 | 51 | 29 | 15 | 0 |
| Religious Worship | 28 | 22 | 12 | 6 | 0 |
| Service | 51 | 40 | 23 | 11 | 0 |
| Warehouse and Storage | 30 | 23 | 13 | 7 | 0 |

(3) For multi-family high-rise residential buildings, the maximum allowable fossil fuel-generated energy

consumption in kBtu per ft² is listed in Table 2.

TABLE 2—MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING TYPE, MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS, kBtu/ft²

| Building type | kBtu/ft ² by fiscal year for which design for construction began | | | | |
|--|---|--------------|--------------|--------------|--------------------|
| | FY 2012–2014 | FY 2015–2019 | FY 2020–2024 | FY 2025–2029 | FY 2030 and beyond |
| Multi-Family in 2–4 Unit Buildings | 47 | 37 | 21 | 11 | 0 |
| Multi-Family in 5 or More Unit Buildings | 42 | 33 | 19 | 9 | 0 |

(4) For buildings that combine one or more building types within or between Tables 1 and 2, area-weighted fossil fuel-generated energy consumption may be calculated by multiplying the floor area of each building type by the consumption value from the appropriate table for that building type, then dividing by the total floor area of the combined building types.

(5) For Federal buildings that do not fit into any of the building type categories listed in Table 1 or Table 2 of § 433.4, a baseline fossil fuel-generated energy consumption shall be calculated using the Performance Rating Method, Appendix G of ASHRAE Standard 90.1–2004, as outlined in § 433.5. The maximum allowable fossil fuel-generated energy consumption for

the proposed design shall be calculated by using the following formula:

$$\text{Maximum Allowable Fossil Fuel-Generated Energy Consumption} = ((\text{Baseline Design Electricity Consumption} \times \text{Electricity Source Energy Factor} \times \text{Electricity Fossil Fuel-Generation Ratio}) + \text{Baseline Design Direct Fossil Fuel Consumption}) \times \text{Fossil Fuel Reduction Multiplier}$$

(6) The fossil fuel reduction multiplier in the formula above shall be taken from Table 3.

TABLE 3—FOSSIL FUEL REDUCTION MULTIPLIER BY FISCAL YEAR FOR WHICH DESIGN FOR CONSTRUCTION BEGAN

| Fiscal year | Reduction multiplier |
|-----------------------|----------------------|
| 2012–2014 | 0.45 |
| 2015–2019 | 0.35 |
| 2020–2024 | 0.20 |
| 2025–2029 | 0.10 |
| 2030 and beyond | 0.00 |

(7) All building energy usage, including estimated receptacle and plug loads, must be included in the calculation in Table 3 of this section.

(f)(1) Upon petition by an agency subject to this section, the Secretary may adjust the applicable numeric requirement in paragraph (e) of this section with respect to a specific building if:

(i) The head of the agency designing the building certifies in writing that meeting such requirement would be technically impracticable in light of the agency’s specified functional needs for that building;

(ii) The head of the agency designing the building demonstrates that the requested adjustment is the largest feasible reduction in fossil fuel-generated consumption that can reasonably be achieved; and

(iii) The Secretary concurs with the agency’s conclusion.

(2) This adjustment shall not apply to the General Services Administration.

6. Section 433.5 is revised to read as follows:

§ 433.5 Performance level determination.

(a) For new Federal commercial and multi-family high-rise residential buildings whose design for construction began on or after January 3, 2007, each Federal agency shall determine energy consumption levels for both the baseline and proposed building by using the Performance Rating Method found in Appendix G of ANSI/ASHRAE/IESNA Standard 90.1–2004, (incorporated by reference; see § 433.3), except the formula for calculating the Performance Rating in paragraph G1.2 shall read as follows:

$$\text{Percentage improvement} = 100 \times \frac{\text{Baseline building consumption} - \text{Proposed building consumption}}{\text{Baseline building consumption} - \text{Receptacle and process loads}}$$

(b) Each Federal agency shall consider laboratory fume hoods and kitchen

ventilation systems as part of the ASHRAE-covered HVAC loads subject to the 30 percent savings requirements in this section, rather than as process loads.

(c) Subject to § 433.4(d), each Federal agency shall calculate the fossil fuel-generated energy consumption of a proposed design by the following formula:

$$\text{Proposed Design Fossil Fuel-Generated Energy Consumption} = (\text{Proposed Design Electricity Consumption} \times \text{Electricity Source Energy Factor} \times \text{Electricity Fossil Fuel-Generation Ratio}) + \text{Direct Fossil Fuel Consumption of Proposed Design}$$

(d) Subject to § 433.4(d), if the fossil fuel-generated energy consumption of the proposed design is equal to or less than the applicable maximum allowable fossil fuel-generated energy consumption value in § 433.4(e), the proposed design complies with the fossil fuel-generated consumption reduction requirement in § 433.4. If the fossil fuel-generated energy consumption of the proposed design is greater than the applicable maximum allowable fossil fuel-generated energy consumption value in § 433.4(e), the proposed design does not comply with the fossil fuel-generated energy consumption reduction requirement in § 433.4, and the agency must either modify the design until the design complies with the requirement, or request and receive approval from the Secretary for a downward adjustment of the requirement.

PART 435—ENERGY EFFICIENCY AND FOSSIL FUEL-GENERATED ENERGY CONSUMPTION REDUCTION DESIGN STANDARDS FOR NEW AND MAJOR RENOVATIONS TO FEDERAL LOW-RISE RESIDENTIAL BUILDINGS

7. The authority citation for part 435 continues to read as follows:

Authority: 42 U.S.C. 6831–6832; 6834–6836; 42 U.S.C. 8253–54; 42 U.S.C. 7101 *et seq.*

Subpart A—Mandatory Energy Efficiency and Fossil Fuel-Generated Energy Consumption Reduction Design Standards for Federal Low-Rise Residential Buildings

8. The headings for part 435 and subpart A are revised to read as set forth above.

9. Section 435.1 is revised to read as follows:

§ 435.1 Purpose and scope.

This part establishes an energy efficiency performance and maximum allowable fossil fuel-generated energy

consumption standard for new Federal low-rise residential buildings, for which design for construction began on or after January 3, 2007 (except as otherwise indicated: fossil fuel-generated energy requirements are applicable one year after publication of the final rule, as required by section 305(a) of the Energy Conservation and Production Act, as amended (42 U.S.C. 6834(a)). Additionally, this part establishes certain requirements applicable to major renovations of Federal low-rise buildings, as indicated. For renovated buildings, those requirements apply only to the portions of the building or building systems that are being renovated and to the extent that the scope of the renovation permits compliance with the applicable requirements in this rule. Unaltered portions of the building or building systems are not required to comply with this rule.

10. Section 435.2 is amended by adding in alphabetical order new definitions for “Direct fossil fuel consumption,” “District Energy System,” “Electricity fossil fuel-generation ratio,” “Electricity source energy factor,” “Fossil fuel,” “Fossil fuel consumption for electricity generation,” “Fossil fuel-generated energy consumption,” and “Primary electrical energy consumption” to read as follows:

§ 435.2 Definitions.

* * * * *

Direct fossil fuel consumption means the total fossil fuel consumption in a building excluding primary electrical energy consumption. This includes any fossil fuel consumption resulting from a district energy system used in a building.

District Energy System means a central energy conversion plant and transmission and distribution system that provides thermal energy to a group of buildings (heating via hot water or steam, and/or cooling via chilled water). This definition includes only thermal energy systems; central energy supply systems that provide only electricity are excluded from this definition.

* * * * *

Electricity fossil fuel-generation ratio means the fraction of national U.S. electricity generation from fossil fuel as provided by the Energy Information Administration Electric Power report for the appropriate year.

Electricity source energy factor is the ratio of primary electrical energy consumed to generate and deliver energy to a site to the electrical energy consumed on site. Electricity source energy factor may be calculated by dividing the average utility delivery

ratio in Table 6.2.4 of the DOE Building Energy Data Book for the appropriate year by 3412 to convert the value from Btu/kWh to kWh/kWh.

* * * * *

Fossil fuel means a fuel formed in the earth from plant or animal remains. Fossil fuels include coal, oil, natural gas, kerosene, and liquefied petroleum gas (LPG).

Fossil fuel consumption for electricity generation means the primary electrical energy consumption in a building supplied from the national power grid multiplied by the electricity fossil fuel-generation ratio. Electricity generated completely from non-fossil fuel sources or from a dedicated source not connected to the national power grid is excluded from this definition.

Fossil fuel-generated energy consumption means the sum of direct fossil fuel consumption plus fossil fuel consumption for electricity generation.

* * * * *

Primary electrical energy consumption means the total amount of energy used to generate and deliver electrical energy to a building from the national power grid.

* * * * *

11. Section 435.4 is amended by adding new paragraphs (d), (e), and (f) to read as follows:

§ 435.4 Energy efficiency performance standard.

* * * * *

(d) All Federal agencies shall design new Federal low-rise residential buildings and major renovations to Federal low-rise residential buildings, for which design for construction began at least one year after publication of the

final rule, to meet the requirements of paragraph (e) of this section if:

(1) The subject building is a public building as defined in 40 U.S.C. 3301 and for which transmittal of a prospectus to Congress is required under 40 U.S.C. 3307; or

(2) The cost of the building or major renovation is at least \$2,500,000 (in 2007 dollars, adjusted for inflation).

(e)(1) All Federal agencies shall design new Federal low-rise residential buildings or major renovations of Federal low-rise residential buildings for which design for renovation began at least one year after publication of the final rule and that are classified in paragraph (d) of this section, to meet fossil fuel-generated energy consumption values equal to or lesser than the values shown in Table 1. The maximum allowable fossil fuel-generated energy consumption values in Table 1 area function of housing type and fiscal year for which design for construction began.

(2) For the purpose of this paragraph (e), the following definitions apply:

(i) *Manufactured home* means a housing unit built to the Federal Manufactured Home Construction and Safety Standards in 24 CFR part 3280, that is built on a permanent chassis and moved to a site. It may be placed on a permanent or temporary foundation and may contain one or more rooms.

(ii) *Multi-family in 2–4 unit buildings* means a unit in a building with two to four housing units—a structure that is divided into living quarters for two, three, or four families or households in which one household lives above or beside another. This category also includes houses originally intended for occupancy by one family (or for some

other use) that have since been converted to separate dwellings for two to four families. This includes modular homes but does not include manufactured homes.

(iii) *Multi-family in 5 or more unit buildings* means a unit in a building with five or more housing units—a structure that contains living quarters for five or more households or families and in which one household lives above or beside another. This includes modular homes but does not include manufactured homes.

(iv) *Single-family attached* means a housing unit connected to another housing unit, generally with a shared wall, that provides living space for one household or family. Attached houses are considered single-family houses as long as they are not divided into more than one housing unit and they have an independent outside entrance. A single-family house is contained within walls extending from the basement (or the ground floor, if there is no basement) to the roof. Townhouses, rowhouses, and duplexes are considered single-family attached housing units, as long as there is no household living above another one within the walls extending from the basement to the roof to separate the units. This includes modular homes but does not include manufactured homes.

(v) *Single-family detached* means a separate, unconnected housing unit, not sharing a wall with any other building or housing unit, that provides living space for one household or family. A single-family house is contained within walls extending from the basement (or the ground floor, if there is no basement) to the roof. This includes modular homes but does not include manufactured homes.

TABLE 1—MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING TYPE, LOW-RISE RESIDENTIAL BUILDINGS, kBtu/ft²

| Building type | kBtu/ft ² by Fiscal year for which design for construction began | | | | |
|--|---|--------------|--------------|--------------|-------------------|
| | FY 2012–2014 | FY 2015–2019 | FY 2020–2024 | FY 2025–2029 | FY2030 and beyond |
| Single-Family Detached | 27 | 21 | 12 | 6 | 0 |
| Single-Family Attached | 30 | 23 | 13 | 7 | 0 |
| Multi-Family in 2–4 Unit Buildings | 47 | 37 | 21 | 11 | 0 |
| Multi-Family in 5 or More Unit Buildings | 42 | 33 | 19 | 9 | 0 |
| Manufactured Homes | 52 | 40 | 23 | 12 | 0 |

(3) For Federal buildings that do not fit into any of the building type categories listed in Table 1 of § 435.4, a baseline fossil fuel-generated energy consumption shall be calculated using the Simulated Performance Alternative outlined in § 435.5. The maximum allowable fossil fuel-generated energy

consumption for the proposed design shall be calculated by using the following formula:

Maximum Allowable Fossil Fuel-Generated Energy Consumption = ((Baseline Design Electricity Consumption × Electricity Source Energy Factor × Electricity Fossil

Fuel-Generation Ratio) + Baseline Design Direct Fossil Fuel Consumption) × Fossil Fuel Reduction Multiplier

(4) The fossil fuel reduction multiplier in the formula above shall be taken from Table 2.

TABLE 2—FOSSIL FUEL REDUCTION MULTIPLIER BY FISCAL YEAR FOR WHICH DESIGN FOR CONSTRUCTION BEGAN

| Fiscal year | Reduction multiplier |
|-----------------------|----------------------|
| 2012–2014 | 0.45 |
| 2015–2019 | 0.35 |
| 2020–2024 | 0.20 |
| 2025–2029 | 0.10 |
| 2030 and beyond | 0.00 |

(5) All building energy usage, including estimated receptacle and plug loads, must be included in the calculation in Table 2 of this section.

(f)(1) Upon petition by an agency subject to this section, the Secretary may adjust the applicable numeric requirement in paragraph (e) of this section with respect to a specific building, if:

(i) The head of the agency designing the building certifies in writing that meeting such requirement would be technically impracticable in light of the agency's specified functional needs for that building;

(ii) The head of the agency designing the building demonstrates that the requested adjustment is the largest feasible reduction in fossil fuel-generated consumption that can reasonably be achieved; and

(iii) The Secretary concurs with the agency's conclusion.

(2) This adjustment shall not apply to the General Services Administration.

12. Section 435.5 is revised to read as follows:

§ 435.5 Performance level determination.

(a) For new Federal low-rise residential buildings whose design for construction started on or after January 3, 2007, each Federal agency shall determine energy consumption levels for both the baseline building and proposed building by using the Simulated Performance Alternative found in section 404 of the ICC International Energy Conservation Code, 2004 Supplement Edition, January 2005 (incorporated by reference; see § 435.3).

(b) Subject to § 435.4(d), each Federal agency shall calculate the fossil fuel-generated energy consumption of a proposed design by the following formula:

Proposed Design Fossil Fuel-Generated Energy Consumption = (Proposed Design Electricity Consumption × Electricity Source Energy Factor × Electricity Fossil Fuel-Generation Ratio) + Direct Fossil Fuel Consumption of Proposed Design

(c) Subject to § 435.4(d), if the fossil fuel-generated energy consumption of

the proposed design is equal to or less than the applicable maximum allowable fossil fuel-generated energy consumption value in § 435.4(e), the proposed design complies with the fossil fuel-generated energy consumption reduction requirement in § 435.4. If the fossil fuel-generated energy consumption of the proposed design is greater than the applicable maximum allowable fossil fuel-generated energy consumption value in § 435.4(e), the building does not comply with the fossil fuel-generated energy consumption reduction requirement in § 435.4, and the agency must either modify the design until the design complies with the requirement, or request and receive approval from the Secretary for a downward adjustment of the requirement.

[FR Doc. 2010–25852 Filed 10–14–10; 8:45 am]

BILLING CODE 6450–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 115

RIN 3245–AG14

Surety Bond Guarantee Program; Timber Sales

AGENCY: Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The Small Business Administration (SBA) proposes to amend its Surety Bond Guarantee Program rules to guarantee performance bonds for timber sale contracts awarded by the Federal Government or other public or private landowners.

DATES: Comments must be received on or before November 15, 2010.

ADDRESSES: You may submit comments, identified by RIN 3245–AG14, by any of the following methods:

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

Mail: Office of Surety Guarantees, Suite 8600, 409 Third Street, SW., Washington, DC 20416.

Hand Delivery/Courier: Office of Surety Guarantees, 409 Third Street, SW., Washington, DC 20416.

SBA will post all comments on <http://www.regulations.gov>. If you wish to submit confidential business information (CBI) as defined in the User Notice at <http://www.regulations.gov>, please submit information to Ms. Barbara Brannan, Special Assistant, Office of Surety Guarantees, 409 Third Street, SW., Washington, DC 20416 or send an e-mail to Barbara.brannan@sba.gov. Highlight the

information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Brannan, Office of Surety Guarantees, 202–205–6545, e-mail: Barbara.brannan@sba.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information

The Forest Service of the U.S. Department of Agriculture (USDA) manages the National Forest System, and may permit the harvesting of timber on National Forest System lands in exchange for the payment of an agreed upon sum of money. More information on that program is available at the Web site of the USDA Forest Service at <http://www.fs.fed.us>. Under regulations issued by the Forest Service, these timber sale contracts may require the purchaser to furnish a performance bond for satisfactory compliance with the contract terms. 36 CFR 223.35. Generally, the Performance Bond, as defined in 13 CFR 115.10, ensures that the Principal, as defined in 13 CFR 115.10, complies with all contract terms and conditions associated with forest management, such as the protection of natural resources, soil, water, erosion control, and road maintenance, as well as to ensure the Principal does not cut any trees that are expressly excluded from harvesting in the contract. In the process of cutting and transporting the logs, for example, forest roads may be damaged and the Principal is responsible for repairing the roads. The performance period for most timber sale contracts ranges from one to three years, and some can exceed five years.

With respect to a Performance Bond involving the sale of timber on land managed by USDA, the Federal Government is the Oblige, as defined in 13 CFR 115.10, and the purchaser of the timber is the Principal. Unlike the typical contract for supplies or services where the Oblige pays the Principal for providing supplies or rendering services, the Principal in the timber sale contract is paying the Oblige for the right to cut the designated trees. However, under the definition of "Contract" in 13 CFR 115.10, a contract for which SBA may issue a Surety Bond Guarantee cannot include a contract requiring any payment by the Principal to the Oblige. Thus, SBA cannot presently guarantee a bond for a timber sales contract.

SBA is proposing to amend this definition to permit SBA to issue a bond guarantee for a contract that requires the Principal to pay the Obligees for the harvesting of timber. This action is being taken in response to concerns expressed by small businesses that have experienced difficulty obtaining the required bonds for public and private timber sale contracts. Discussions with representatives of the United States Forest Service confirm the need for increased bonding support for small businesses in this area, and it is estimated that approximately 150 small businesses would be eligible for bond guarantee assistance as a result of implementing this Proposed Rule. This change would apply to contracts involving forests managed by the Federal Government or other public or private landowners. SBA invites comments from public and private entities and individuals on how this proposed rule would affect them.

II. Section-by-Section Analysis

Section 115.10. SBA is proposing to revise the definition of the term “Contract” to allow SBA to issue a performance bond guarantee for a contract that requires the Principal to pay the Obligees for the harvesting of timber on the land of the Obligees. The current definition excludes any contract that requires payment by the Obligees to the Principal. Because this kind of payment is inherent in timber sale contracts, the proposed change makes it clear that timber sale contracts are eligible for performance bond guarantees.

Compliance With Executive Orders 12866, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule does not constitute a significant regulatory action under Executive Order 12866. This rule is also not a major rule under the Congressional Review Act.

Executive Order 12988

This action meets applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

For purposes of Executive Order 13132, SBA has determined that the 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, for the purpose of Executive Order 13132, Federalism, SBA has determined that this Proposed Rule has no federalism implications warranting preparation of a federalism assessment; however, SBA invites comments from the public on this issue.

Paperwork Reduction Act, 44 U.S.C., Ch. 35

SBA has determined that this Proposed Rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of this rule on small entities. However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Within the meaning of RFA, SBA certifies that this rule will not have a significant economic impact on a substantial number of small entities. It is estimated that approximately 150 small businesses would now be eligible for bond guarantee assistance from SBA as a result of implementing this Proposed Rule. Additionally, there are 17 Sureties that participate in the SBG Program, and no part of this Proposed Rule would impose any significant additional cost or burden on them.

List of Subjects in 13 CFR Part 115

Claims, Small businesses, Surety bonds.

For the reasons stated in the preamble, SBA proposes to amend 13 CFR part 115 as follows:

PART 115—SURETY BOND GUARANTEE

1. The authority citation for part 115 continues to read as follows:

Authority: 5 U.S.C. app. 3, 15 U.S.C. 687b, 687c, 694b, 694b note, Pub. L. 106–554; and Pub. L. 108–447, Div. K, Sec. 203.

2. Amend § 115.10 by revising the third sentence of the definition “Contract” to read as follows:

§ 115.10 Definitions.

* * * * *

Contract * * * A Contract does not include a permit, subdivision contract, lease, land contract, evidence of debt, financial guarantee (e.g., a contract requiring any payment by the Principal to the Obligees, except for contracts for the sale of timber that require the Principal to pay the Obligees), warranty of performance or efficiency, warranty of fidelity, or release of lien (other than for claims under a guaranteed bond).

* * * * *

Dated: October 8, 2010.

Karen G. Mills,
Administrator.

[FR Doc. 2010–25999 Filed 10–14–10; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0959; Directorate Identifier 2010–NM–119–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

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

There have been two in-service reports of main landing gear (MLG) tire failure on landing, during which a flailing tire tread caused damage to No. 2 and No. 3 hydraulic system lines in the wing auxiliary spar area on the left side of the aircraft. This damage resulted in the loss of supply pressure to the inboard and outboard brakes, as the only remaining braking source available was the No. 3 hydraulic system accumulator. The degradation of the brake system performance could adversely affect the aircraft during landing.

* * * * *

The unsafe condition is loss of braking capability, which could reduce the ability of the flightcrew to safely land the airplane. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 29, 2010.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; e-mail thd.crj@aero.bombardier.com; Internet <http://www.bombardier.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT:

Christopher Alfano, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7340; fax (516) 794-5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2010-0959; Directorate Identifier 2010-NM-119-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF-2010-10, dated March 26, 2010 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

There have been two in-service reports of main landing gear (MLG) tire failure on landing, during which a flailing tire tread caused damage to No. 2 and No. 3 hydraulic system lines in the wing auxiliary spar area on the left side of the aircraft. This damage resulted in the loss of supply pressure to the inboard and outboard brakes, as the only remaining braking source available was the No. 3 hydraulic system accumulator. The degradation of the brake system performance could adversely affect the aircraft during landing.

This directive mandates the relocation of the No. 2 and No. 3 hydraulic system lines in the wing auxiliary spar area on the left side of the aircraft, together with a modification to the left wing rib and debris shield, in order to prevent damage to the hydraulic lines in the event of a MLG tire failure. The debris shield on the right side is also modified for part commonality.

The unsafe condition is loss of braking capability, which could reduce the ability of the flightcrew to safely land the airplane. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Bombardier, Inc. has issued Service Bulletins 700-29-021 and 700-1A11-29-004, both Revision 01, both dated January 25, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 115 products of U.S. registry. We also estimate that it would take about 40 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$4,855 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$949,325, or \$8,255 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2010–0959; Directorate Identifier 2010–NM–119–AD.

Comments Due Date

(a) We must receive comments by November 29, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes, serial numbers 9002 through 9401 inclusive, certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 29: Hydraulic power.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

There have been two in-service reports of main landing gear (MLG) tire failure on landing, during which a flailing tire tread caused damage to No. 2 and No. 3 hydraulic system lines in the wing auxiliary spar area on the left side of the aircraft. This damage resulted in the loss of supply pressure to the inboard and outboard brakes, as the only remaining braking source available was the No. 3 hydraulic system accumulator. The degradation of the brake system performance could adversely affect the aircraft during landing.

* * * * *

The unsafe condition is loss of braking capability, which could reduce the ability of the flightcrew to safely land the airplane.

Compliance

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

Actions

(g) Within 30 months after the effective date of this AD, relocate the No. 2 and No. 3 hydraulic system lines in the wing auxiliary spar area on the left side of the aircraft, and modify the left wing rib and left and right debris shields, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–29–021 (for Model BD–700–1A10 airplanes) or 700–1A11–29–004 (for Model BD–700–1A11 airplanes), both Revision 01, both dated January 25, 2010, as applicable.

Credit for Actions Accomplished in Accordance With Previous Service Information

(h) Actions accomplished before the effective date of this AD in accordance with Bombardier Service Bulletin 700–29–021 or 700–1A11–29–004, both dated April 3, 2009, as applicable, are considered acceptable for compliance with the corresponding actions specified in this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(i) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York, 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(j) Refer to MCAI Canadian Airworthiness Directive CF–2010–10, dated March 26, 2010; and Bombardier Service Bulletins 700–29–021 and 700–1A11–29–004, both Revision 01, both dated January 25, 2010; for related information.

Issued in Renton, Washington, on October 6, 2010.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–25921 Filed 10–14–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–1023; Directorate Identifier 2010–CE–055–AD]

RIN 2120–AA64

Airworthiness Directives; Embraer—Empresa Brasileira de Aeronautica S.A. Model EMB–500 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the

products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been detected a short circuit in harness W101 due to its interference with the main door mechanism. Further analysis of the affected region has also revealed the possibility of chafing between the same harness and the oxygen tubing. The chafing of the wiring harness against the oxygen tubing could lead to a short circuit of the wiring harness and a subsequent fire in the airplane.

Since this condition may occur in other airplanes of the same type and affects flight safety, a corrective action is required. Thus, sufficient reason exists to request compliance with this AD in the indicated time limit.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by November 29, 2010.

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

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

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4146; fax: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2010-1023; Directorate Identifier 2010-CE-055-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The AGÊNCIA NACIONAL DE AVIAÇÃO CIVIL—BRAZIL, which is the aviation authority for Brazil, has issued AD No.: 2010-09-02, dated October 17, 2010 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

It has been detected a short circuit in harness W101 due to its interference with the main door mechanism. Further analysis of the affected region has also revealed the possibility of chafing between the same harness and the oxygen tubing. The chafing of the wiring harness against the oxygen tubing could lead to a short circuit of the wiring harness and a subsequent fire in the airplane.

Since this condition may occur in other airplanes of the same type and affects flight safety, a corrective action is required. Thus, sufficient reason exists to request compliance with this AD in the indicated time limit.

The MCAI requires installing clamps to the W101 wiring harness. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Empresa Brasileira de Aeronáutica S.A. (EMBRAER) has issued Service Bulletin No. SB 500-24-0002, dated March 8, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA’s Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our

bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 83 products of U.S. registry. We also estimate that it would take about 12 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$13 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$85,739, or \$1,033 per product.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Empresa Brasileira de Aeronautica S.A. (EMBRAER); Docket No. FAA-2010-1023; Directorate Identifier 2010-CE-055-AD.

Comments Due Date

(a) We must receive comments by November 29, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB-500 airplanes, serial numbers 50000005 thru 50000105, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 92: Wiring Elements.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

It has been detected a short circuit in harness W101 due to its interference with the main door mechanism. Further analysis of the affected region has also revealed the possibility of chafing between the same harness and the oxygen tubing. The chafing of the wiring harness against the oxygen tubing could lead to a short circuit of the wiring harness and a subsequent fire in the airplane.

Since this condition may occur in other airplanes of the same type and affects flight safety, a corrective action is required. Thus, sufficient reason exists to request compliance with this AD in the indicated time limit.

The MCAI requires installing clamps to the W101 wiring harness.

Actions and Compliance

(f) Unless already done, within 600 hours time-in-service (TIS) after the effective date of this AD or within 12 months after the effective date of this AD, whichever comes first, install clamps and protection sleeves to harness W101 within the cockpit area and rework structures to eliminate the fretting spots of the harness with the main door locking mechanism and with the oxygen tube. Do the installation following Empresa Brasileira de Aeronautica S.A. (EMBRAER) Service Bulletin No. SB 500-24-0002, dated March 8, 2010.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4146; fax: (816) 329-4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required

to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI Agência Nacional de Aviação Civil—Brazil (ANAC), AD No.: 2010-09-02, dated October 17, 2010; and Empresa Brasileira de Aeronautica S.A. (EMBRAER) Service Bulletin No. SB 500-24-0002, dated March 8, 2010, for related information.

Issued in Kansas City, Missouri, on October 7, 2010.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010-25924 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 117 and 121

[Docket No. FAA-2009-1093; Notice No. 10-11]

RIN 2120-AJ58

Flightcrew Member Duty and Rest Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Response to requests for a comment period extension.

SUMMARY: The FAA published a Notice of Proposed Rulemaking (NPRM) on September 14, 2010, to amend its existing flight, duty and rest regulations applicable to certificate holders and their flightcrew members. The FAA has received several requests from stakeholders to extend the comment period for filing comments to the proposed rule. This notice provides the FAA's response to those requests. **DATES:** The comment period for the NPRM published on September 14, 2010, at 75 FR 55852, closes on November 15, 2010.

ADDRESSES: You may send comments to the NPRM identified by Docket Number FAA-2009-1093, using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30, U.S. Department of

Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.
- *Hand Delivery:* Bring comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78) or you may visit <http://DocketsInfo.dot.gov>.

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Shirley Stroman, ARM-104, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; e-mail shirley.stroman@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

You may refer to the NPRM published in the **Federal Register** (75 FR 55852) on September 14, 2010 for detailed instructions on filing your comments to the proposed rule and how we will handle them.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

- (1) Searching the Federal eRulemaking Portal at <http://www.regulations.gov>;
- (2) Visiting the Office of Rulemaking's Web page at <http://www.faa.gov/avr/arm/index.cfm>; or
- (3) Accessing the Government Printing Office's Web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

Background

On September 14, 2010, the FAA published an NPRM (75 FR 55852) entitled "Flightcrew Member Duty and Rest Requirements." The proposed regulation recognizes the growing similarities between the types of operations and the universality of factors that lead to fatigue in most individuals. Fatigue threatens aviation safety because it increases the risk of pilot error that could lead to an accident. The new requirements, if adopted, would eliminate the current distinctions between domestic, flag and supplemental operations. The proposal provides different requirements based on the time of day, whether an individual is acclimated to a new time zone, and the likelihood of being able to sleep under different circumstances. The NPRM comment period is scheduled to close on November 15, 2010.

Since publication of the NPRM, the FAA has received several petitions to extend the comment period. Requests for extension include those from National Air Carrier Association, Cargo Airline Association (CAA), United Parcel Service (UPS), Atlas Air Worldwide Holdings, Inc., Air Transport Association of America, Inc., (ATA), Air Carrier Association of America, Regional Airline Association, and others. The requests include ones for a 30-day extension, 45-day extension, 60-day extension, and 180-day extension.

In general, the petitioners said the additional time is necessary due to the length and complexity of the NPRM and Regulatory Impact Analysis. Several petitioners, including CAA, UPS, and ATA, also said the recent statutory mandate that requires carriers to submit a Fatigue Risk Management Plan to the FAA by October 30, 2010, will take time and resources away from developing comments to the NPRM.

The FAA has reviewed the requests for an extension of the comment period on the "Flightcrew Member Duty and Rest Requirements" NPRM. While we understand the reasons for these requests, we do not believe an extension is necessary for the reasons stated below.

FAA Response to Comment Period Extension Requests

In 2009, the FAA established the Flight and Duty Time Limitations and Rest Requirements Aviation Rulemaking Committee (ARC). The ARC provided a forum for the aviation industry to give extensive input on revising current flight and duty time limitations regulations. Therefore, the FAA does not believe it is necessary to extend the comment period for the proposed rule. Consequently, the requests for an extension of the comment period are denied. Also, in the recently passed Airline Safety and Federal Aviation Administration Extension Act of 2010, Congress mandated that the FAA issue a final rule on pilot fatigue by August 1, 2011. To help ensure that we meet this deadline, the FAA must receive comments to its proposed rule by November 15, 2010. However, as stated in Title 14 Code of Federal Regulations § 11.45, we will consider comments filed late if it is possible to do so without incurring expense or delay.

The requests for extension and this Notice will be included in the rulemaking docket.

Issued in Washington, DC, on October 12, 2010.

Dennis Pratte,

Acting Deputy Director, Office of Rulemaking.

[FR Doc. 2010-26142 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Part 701

RIN 1240-AA02

Regulations Implementing the Longshore and Harbor Workers' Compensation Act: Recreational Vessels

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Office of Workers' Compensation Programs (OWCP) is republishing the Notice of Proposed Rulemaking entitled Longshore and Harbor Workers' Compensation Act: Recreational Vessels, published on August 17, 2010 (75 FR 50718), and affording the public an additional period for submitting comments. This document contains proposed regulations implementing amendments to the Longshore and Harbor Workers'

Compensation Act (LHWCA) by the American Recovery and Reinvestment Act of 2009 (ARRA), relating to the exclusion of certain recreational-vessel workers from the LHWCA's definition of "employee." These regulations would clarify both the definition of "recreational vessel" and those circumstances under which workers are excluded from LHWCA coverage when working on those vessels. The proposed rules also codify the Department's longstanding view that employees are covered under the LHWCA so long as some of their work constitutes "maritime employment" within the meaning of the statute.

DATES: The Department invites written comments on the proposed rule from interested parties. The Department is particularly interested in receiving comments regarding the proposed definition of "recreational vessel." When first published, the Department set October 18, 2010 as the deadline for comments on the NPRM, which afforded the public 60 days to submit comments. 75 FR 50718 (Aug. 17, 2010). As explained in the supplementary information section below, the Department is republishing the NPRM to accommodate revising the title of 20 CFR chapter VI. The Department is also effectively lengthening the comment period by 30 days. The Department believes that the combined comment period—a total of 90 days—will allow interested members of the public sufficient time to review the NPRM and submit comments. Accordingly, written comments must be received by November 17, 2010.

ADDRESSES: You may submit written comments, identified by RIN number 1240-AA02, by any of the following methods. To facilitate the receipt and processing of comment letters, OWCP encourages interested parties to submit their comments electronically.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions on the Web site for submitting comments.

- *Facsimile:* (202) 693-1380 (this is not a toll-free number). Only comments of ten or fewer pages (including a FAX cover sheet and attachments, if any) will be accepted by FAX.

- *Regular Mail:* Submit comments on paper, disk, or CD-ROM to the Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C-4315, 200 Constitution Avenue, NW., Washington, DC 20210. The Department's receipt of U.S. mail may be significantly delayed due to security procedures. You must

take this into consideration when preparing to meet the deadline for submitting comments.

- *Hand Delivery/Courier:* Submit comments on paper, disk, or CD-ROM to the Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C-4315, 200 Constitution Avenue, NW., Washington, DC 20210.

Instructions: All submissions received must include the agency name and the Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: To read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Michael Niss, Director, Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C-4315, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693-0038 (this is not a toll-free number). TTY/TDD callers may dial toll free 1-800-877-8339 for further information.

SUPPLEMENTARY INFORMATION:

I. Background of This Rulemaking

A. Statutory Background

Section 2(3) of the LHWCA defines "employee" to mean "any person engaged in maritime employment, including any longshoreman or other person engaged in longshoring operations, and any harbor-worker including a ship repairman, shipbuilder, and ship-breaker * * *" 33 U.S.C. 902(3). The remainder of this provision, initially enacted as part of the 1984 amendments to the LHWCA, lists eight categories of workers who are excluded from the definition of "employee" and therefore excluded from LHWCA coverage. 33 U.S.C. 902(3)(A)-(H). Section 2(3)(F) in particular excluded from coverage "individuals employed to build, repair, or dismantle any recreational vessel under sixty-five feet in length," provided that such individuals were "subject to coverage under a State workers' compensation law." 33 U.S.C. 902(3)(F).

Section 803 of Title IX of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115, 127 (2009), amended the section 2(3)(F) exclusion. That provision now excludes "individuals employed to build any recreational vessel under sixty-five feet in length, or individuals employed to repair any recreational

vessel, or to dismantle any part of a recreational vessel in connection with the repair of such vessel," and retains the State-workers'-compensation-coverage proviso. 33 U.S.C. 902(3)(F), as amended by Public Law 111-5 section 803, 123 Stat 115, 187 (2009) (emphasis supplied).

Thus, under the original version of section 2(3)(F), all individuals working on recreational vessels shorter than sixty-five feet were excluded from the definition of "employee." The amended exclusion retains this same rule for employees building recreational vessels. For individuals who repair or dismantle recreational vessels, however, the amended exclusion provides for different treatment. Now, workers who repair recreational vessels or dismantle them for repair are excluded from the definition of "employee" regardless of the vessel's length. With the removal of the sixty-five feet length limit, the number of vessels that will be considered recreational for LHWCA purposes will increase; and as vessel numbers increase, the number of workers who repair or dismantle them for repair will naturally increase as well. On the other hand, amended section 2(3)(F) no longer excludes workers who dismantle recreational vessels, except when the dismantling is in connection with a repair. Thus, some workers previously excluded may now be considered "employees" under section 2(3).

The proposed regulations clarify how amended section 2(3)(F) should be interpreted and applied in several respects.

B. Reasons for Republication

The NPRM proposes revisions to regulations contained in 20 CFR chapter VI governing the administration of the LHWCA and its extensions, and the Black Lung Benefits Act (BLBA). When the NPRM was initially published on August 17, 2010, Chapter VI was titled "Employment Standards Administration, Department of Labor." Because the Secretary dissolved the Employment Standards Administration on November 8, 2009 (*see* Secretary's Order 10-2009, 74 FR 58834 (Nov. 13, 2009)), that title was no longer accurate. The Department has now issued a final rule revising the title to reflect the Secretary's delegation of her authority to administer the LHWCA and its extensions, and the BLBA to the Director, OWCP. Accordingly, OWCP is republishing the NPRM under the current Chapter VI title, "Office of Workers' Compensation Programs, Department of Labor (Divisions of Longshore and Harbor Workers'

Compensation and Coal Mine Workers' Compensation)."

II. Summary of the Proposed Rule

The Department summarized each proposed regulation in the August 17, 2010 NPRM. 75 FR 50719–24. Those summaries apply with equal force to this republished NPRM.

III. Statutory Authority

The Department's statement of its statutory authority for proposing these rules is set forth in the August 17, 2010 NPRM. 75 FR 50724.

IV. Other Legal Analyses

The Department's analysis of the following legal requirements is set forth in the August 17, 2010 NPRM:

- A. Information Collection Requirements (subject to the Paperwork Reduction Act) Imposed under the Proposed Rule, 75 FR 50724.
- B. Executive Order 12866 (Regulatory Planning and Review), 75 FR 50724.
- C. Small Business Regulatory Enforcement Fairness Act of 1996, 75 FR 50725.
- D. Unfunded Mandates Reform Act of 1995, 75 FR 50725.
- E. Regulatory Flexibility Act and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking), 75 FR 50725–28.
- F. Executive Order 13132 (Federalism), 75 FR 50728.
- G. Executive Order 12988 (Civil Justice Reform), 75 FR 50728.
- H. Congressional Review Act, 75 FR 50728.

List of Subjects in 20 CFR Part 701

Longshore and harbor workers, Organization and functions (government agencies), Workers' compensation.

For the reasons set forth in the preamble, the Department of Labor proposes to amend 20 CFR part 701 as follows:

PART 701—GENERAL; ADMINISTERING AGENCY; DEFINITIONS AND USE OF TERMS

1. The authority citation for part 701 is revised to read as follows:

Authority: 5 U.S.C. 301 and 8171 *et seq.*; 33 U.S.C. 939; 36 DC Code 501 *et seq.*; 42 U.S.C. 1651 *et seq.*; 43 U.S.C. 1331; Reorganization Plan No. 6 of 1950, 15 FR 3174, 3 CFR, 1949–1953 Comp., p. 1004, 64 Stat. 1263; Secretary's Order 10–2009; Pub. L. 111–5 § 803, 123 Stat. 115, 187 (2009).

2. Revise the undesignated center heading following § 701.203 to read as follows:

Definitions and Use of Terms

* * * * *

2a. Amend § 701.301 as follows:
 a. Revise the section heading;
 b. Redesignate paragraph (a)(12) as § 701.302, with its sub-paragraphs redesignated according to the following table:

| Former designation in § 701.301 | New designation in § 701.302 |
|---------------------------------|------------------------------|
| (a)(12)(i) introductory text. | (a) introductory text. |
| (a)(12)(i)(A) | (a)(1). |
| (a)(12)(i)(B) | (a)(2). |
| (a)(12)(i)(C) | (a)(3). |
| (a)(12)(ii) introductory text. | (b) introductory text. |
| (a)(12)(ii)(A) | (b)(1). |
| (a)(12)(ii)(B) | (b)(2). |
| (a)(12)(iii) introductory text. | (c) introductory text. |
| (a)(12)(iii)(A) | (c)(1). |
| (a)(12)(iii)(B) | (c)(2). |
| (a)(12)(iii)(C) | (c)(3). |
| (a)(12)(iii)(D) | (c)(4). |
| (a)(12)(iii)(E) | (c)(5). |
| (a)(12)(iii)(F) | (c)(6). |

c. Redesignate paragraphs (a)(13) through (a)(16) as (a)(12) through (a)(15). The revision reads as follows:

§ 701.301 What do certain terms in this subchapter mean?

* * * * *

3. Amend newly designated § 701.302 by adding a section heading, and by revising paragraph (c)(6) to read as follows:

§ 701.302 Who is an employee?

* * * * *

(c) * * *
 (6) Individuals employed to build any recreational vessel under sixty-five feet in length, or individuals employed to repair any recreational vessel, or to dismantle any part of a recreational vessel in connection with the repair of such vessel. For purposes of this paragraph, the special rules set forth at §§ 701.501 through 701.505 apply.

4. Add § 701.303 to read as follows:

§ 701.303 Is a worker who engages in both qualifying "maritime employment" and non-qualifying duties in the course of employment an "employee" covered by the LHWCA?

(a) An individual is a covered "employee" if he or she performs at least some work in the course of employment that qualifies as "maritime employment" and that work is not—

- (1) Infrequent, episodic, or too minimal to be a regular part of his or her overall employment; or
- (2) Otherwise excluded from coverage under § 701.302.

(b) The individual's status as a covered "employee" does not depend on whether he or she was engaged in

qualifying maritime employment or non-qualifying work when injured.
 5. Add a new undesignated center heading following § 701.401 and add § 701.501 to read as follows:

Special Rules for the Recreational Vessel Exclusion From the Definition of "Employee"

§ 701.501 What is a Recreational Vessel?

(a) *Recreational vessel* means a vessel—
 (1) Being manufactured or operated primarily for pleasure; or
 (2) Leased, rented, or chartered to another for the latter's pleasure.
 (b) Recreational vessel does not include a—
 (1) "Passenger vessel" as defined by 46 U.S.C. 2101(22);
 (2) "Small passenger vessel" as defined by 46 U.S.C. 2101(35);
 (3) "Uninspected passenger vessel" as defined by 46 U.S.C. 2101(42);
 (4) Vessel routinely engaged in "commercial service" as defined by 46 U.S.C. 2101(5); or
 (5) Vessel that routinely carries "passengers for hire" as defined by 46 U.S.C. 2101(21a).

(c) All subsequent amendments to the statutes referenced in paragraph (b) of this section are incorporated. The statutes referenced in paragraph (b) and all subsequent amendments thereto apply as interpreted by regulations in Title 46 of the Code of Federal Regulations.

6. Add § 701.502 to read as follows:

§ 701.502 What types of work may exclude a recreational-vessel worker from the definition of "employee"?

(a) An individual who works on recreational vessels may be excluded from the definition of "employee" when:

(1) The individual's date of injury is before February 17, 2009, the injury is covered under a State workers' compensation law, and the individual is employed to:

- (i) Build any recreational vessel under sixty-five feet in length; or
- (ii) Repair any recreational vessel under sixty-five feet in length; or
- (iii) Dismantle any recreational vessel under sixty-five feet in length.

(2) The individual's date of injury is on or after February 17, 2009, the injury is covered under a State workers' compensation law, and the individual is employed to:

- (i) Build any recreational vessel under sixty-five feet in length; or
- (ii) Repair any recreational vessel; or
- (iii) Dismantle any recreational vessel to repair it.

(b) In applying paragraph (a) of this section, the following rules apply:

(1) "Length" means a straight line measurement of the overall length from the foremost part of the vessel to the aftmost part of the vessel, measured parallel to the center line. The measurement must be from end to end over the deck, excluding sheer. Bow sprits, bumpkins, rudders, outboard motor brackets, handles, and other similar fittings, attachments, and extensions are not included in the measurement.

(2) "Repair" means any repair of a vessel including installations, painting and maintenance work. Repair does not include alterations or conversions that render the vessel a non-recreational vessel under § 701.501. For example, a worker who installs equipment on a private yacht to convert it to a passenger-carrying whale-watching vessel is not employed to "repair" a recreational vessel. Repair also does not include alterations or conversions that render a non-recreational vessel recreational under § 701.501.

(3) "Dismantle" means dismantling any part of a vessel to complete a repair but does not include dismantling any part of a vessel to complete alterations or conversions that render the vessel a non-recreational vessel under § 701.501, or render the vessel recreational under § 701.501, or to scrap or dispose of the vessel at the end of the vessel's life.

(c) An individual who performs recreational-vessel work not excluded under paragraph (a) of this section or who engages in other qualifying maritime employment in addition to recreational-vessel work excluded under paragraph (a) of this section will not be excluded from the definition of "employee." (See § 701.303).

7. Add § 701.503 to read as follows:

§ 701.503 Did the American Recovery and Reinvestment Act of 2009 Amend the Recreational Vessel Exclusion?

Yes. The amended exclusion was effective February 17, 2009, the effective date of the American Recovery and Reinvestment Act of 2009.

8. Add § 701.504 to read as follows:

§ 701.504 When does the 2009 amended version of the recreational vessel exclusion apply?

(a) *Date of injury.* Whether the amended version applies depends on the date of the injury for which compensation is claimed. The following rules apply to determining the date of injury:

(1) *Traumatic injury.* If the individual claims compensation for a traumatic injury, the date of injury is the date the employee suffered harm. For example, if the individual injures an arm or leg in

the course of his or her employment, the date of injury is the date on which the individual was hurt.

(2) *Occupational disease or infection.* Occupational illnesses and infections are generally caused by exposure to a harmful substance or condition. If the individual claims compensation for an occupational illness or infection, the date of injury is the date the illness becomes "manifest" to the individual. The injury is "manifest" when the individual learns, or reasonably should have learned, that he or she is suffering from the illness, that the illness is related to his or her work with the responsible employer, and that he or she is disabled as a result of the illness.

(3) *Hearing loss.* If the individual claims compensation for hearing loss, the date of injury is the date the individual receives an audiogram with an accompanying report which indicates the individual has suffered a loss of hearing that is related to employment.

(4) *Death-benefit claims.* If the individual claims compensation for an employee's death, the date of injury is the date of the employee's death, even if his or her death was the result of an event or incident that happened on an earlier date.

(b) If the date of injury is before February 17, 2009, the individual's entitlement is governed by section 2(3)(F) as it existed prior to the 2009 amendment.

(c) If the date of injury is on or after February 17, 2009, the employee's eligibility is governed by the 2009 amendment to section 2(3)(F).

9. Add § 701.505 to read as follows:

§ 701.505 May an employer stop paying benefits awarded prior to the effective date of the recreational vessel exclusion amendment if the employee would now fall within the exclusion?

No. If an individual was awarded compensation for an injury occurring before February 17, 2009, the employer must still pay all benefits awarded, including disability compensation and medical benefits, even if the employee would be excluded from coverage under the amended exclusion.

Shelby Hallmark,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2010-25895 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-CF-P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 67

RIN 1024-AD65

Historic Preservation Certifications for Federal Income Tax Incentives

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) proposes to amend its procedures for obtaining historic preservation certifications for rehabilitation of historic structures. Individuals and corporations must obtain these certifications to be eligible for tax credits from the Internal Revenue Service (IRS). This rule: Incorporates references to the revised sections of the Internal Revenue Code containing the requirements for obtaining a tax credit; replaces references to NPS's regional offices with references to its Washington Area Service Office (WASO); requires NPS to accept appeals for denial of certain certifications; and removes the certification fee schedule from the regulation. These latter two revisions provide an additional avenue for appeals and allow NPS to update fees by publishing a notice in the **Federal Register** as administrative costs change.

DATES: Comments must be received by December 14, 2010.

ADDRESSES: You may submit comments, identified by the number 1024-AD65, by any of the following methods:

—*Federal rulemaking portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
—*Mail:* National Park Service, Attn. Michael J. Auer, 1849 C Street, NW. (org. code 2255), Washington, DC 20240.

All submissions must include the agency name and the number 1024-AD65. We will post all comments without change to <http://www.regulations.gov>, including any personal information provided. For additional information, see "Public Participation" under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Michael J. Auer, National Park Service, 1849 C Street, NW. (org. code 2255), Washington, DC 20240; Michael_Auer@nps.gov; fax: 202-371-1616.

SUPPLEMENTARY INFORMATION:

Background

Section 47 of Title 26 of the United States Code (the Internal Revenue

Code), formerly Section 48(g), authorizes tax credits for qualified expenditures of funds for “certified rehabilitation” of “certified historic structures.” This section of the Internal Revenue Code designates the Secretary of the Interior as the authority for review of applications for certifications to verify: (a) That buildings undergoing rehabilitation are “certified historic structures,” and (b) that the rehabilitation preserves the overall historic character of the buildings, and therefore is a “certified rehabilitation.”

These approvals take the form of notifications or “certifications” by the Secretary of the Interior to the Secretary of the Treasury. In addition, section 170(h) of the Internal Revenue Code allows a Federal income tax deduction for the donation of interests in qualified real property for conservation purposes.

Section 170(h) also designates the Secretary of the Interior as the authority who receives applications and issues certifications verifying to the Secretary of the Treasury that the building or buildings contribute to the significance of a historic district.

The proposed rule accomplishes four objectives. First, it removes outdated references to the Internal Revenue Code. Second, the proposed rule deletes references to the regional offices and substitutes the NPS Washington office in their place. In 1995, the review authority on applications for historic preservation certifications was moved from the NPS regional offices to the Washington office. Third, it lifts the prohibition on appeals from the denial of preliminary certification for rehabilitation of a property that is not a certified historic structure. Removing this prohibition from the language of § 67.10(b) brings the proposed rule into conformity with longstanding agency practice, which has been to grant administrative review in such circumstances.

Fourth, the proposed rule removes the certification fee schedule from the regulation. In 1984, NPS began charging fees for processing and reviewing tax incentives applications. This proposed rule removes the fee schedule from § 67.11 and all other specific provisions regarding the charging of fees from the regulations, and incorporates an explanation of the method by which we will determine the kind and amount of review fees to be charged in the future. We will provide public notice of all fee changes. Until a revised means of determining fees is decided upon, approved, and published, the 1984 fee schedule will remain in effect.

Compliance With Other Laws, Executive Orders, and Department Policies

Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget has determined that this document is not a significant rule. We have made the assessments required by E.O. 12866 and the results are available as a supporting document with the proposed rule at <http://www.regulations.gov>.

(1) The results of the NPS cost/benefit analysis are that this rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. It is an agency-specific rule. No other Federal agency designates “certified historic structures” or “certified rehabilitations” for Federal income tax incentives.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. This rule updates statutory authority, deletes references to regional offices and substitutes the NPS Washington office in their place, authorizes additional administrative appeals, and removes from the text of the regulations the fee dollar amounts and specific instructions for charging fees.

(4) This rule does not raise novel legal or policy issues.

Regulatory Flexibility Act (RFA)

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, (5 U.S.C. 601 *et seq.*).

The NPS threshold analysis as part of the NPS cost-benefit analysis concluded the proposed rule would generate positive benefits for all affected businesses with no negative impacts.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(1) Does not have an annual effect on the economy of \$100 million or more. The rule merely updates statutory authority, revises references to NPS offices, authorizes additional

administrative appeals, and deletes specific dollar amount of application review fees—changes that the Office of Management and Budget (OMB) has determined are purely technical in nature.

(2) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The rule does not impose any new requirements on building owners undertaking building rehabilitations.

(3) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. OMB has determined that the changes proposed in the rule are purely technical. Moreover, the tax incentives program involves purely domestic buildings and entities.

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local or Tribal governments or the private sector.

Although State Historic Preservation Offices receive applications for the Federal tax incentives and forward them to the NPS, with a recommendation, State participation in this program is funded through the Historic Preservation Fund administered by the NPS.

Takings (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. Application for the Federal historic preservation tax incentives program is on a voluntary basis by owners seeking a benefit in the form of Federal income tax incentives. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. The rule does not preempt or conflict with any State or local law. A Federalism impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175)

Under the criteria in Executive Order 13175, we have evaluated this rule and determined that it has no potential effects on Federally recognized Indian tribes. The rule has no Tribal implications, and does not impose any costs on Indian Tribal governments.

Paperwork Reduction Act (PRA)

This rule contains information collection requirements and a submission under the Paperwork Reduction Act is required. OMB has approved the information collection and has assigned approval number 1024-0009, expiring on 03/31/2013. A Federal agency may not conduct or sponsor and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. Part 1 of the application is used in requesting a certification of historic significance or non-significance and preliminary determinations. Part 2 of the application is used in requesting an evaluation of a proposed rehabilitation project or (in conjunction with a request for certification of completed work) a certification of a completed rehabilitation project. Information contained in the application is required to obtain a benefit. We estimate the burden associated with this information collection to be 4.6 hours per response including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the form. Direct your comments regarding this burden estimate or any aspect of this form to the Manager, Administrative Program Center, National Park Service, 1849 C Street, NW., Washington, DC 20240 and to the Office of Management and Budget, Paperwork Reduction Project Number 1024-0009, Washington, DC 20503.

National Environmental Policy Act (NEPA)

This rule is developed under the authority of the National Historic Preservation Act, particularly 16 U.S.C. 470a(a)(1)(A), and 26 U.S.C. 47 (Internal Revenue Code), and does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental

Policy Act of 1969 is not required because the rule is administrative and procedural in nature and therefore is covered by a categorical exclusion under 43 CFR 46.205(b) and 46.210(i).

We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under the National Environmental Policy Act.

Information Quality Act (IQA)

In developing this rule we did not conduct or use a study, experiment, or survey requiring peer review under the Information Quality Act (Pub. L. 106-554).

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Clarity of This Regulation

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, *etc.*

Drafting Information: The primary authors of this regulation are Michael J. Auer, Technical Preservation Services, Heritage Preservation Services, National Park Service; Philip A. Selleck, Chief, Regulations and Special Park Uses, National Park Service; A.J. North, Branch Chief, Regulations and Special Park Uses, Regulations, National Park Service and Maria Elena Lurie, Office of the Solicitor, Department of the Interior.

Public Participation

Before including your address, phone number, e-mail address, or other personal identifying information in your

comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Docket: For access to the electronic docket to read the proposed rule, background documents or e-mail comments received, go to <http://www.regulations.gov> and enter “1024-AD65” in the “Keyword or ID” search box.

List of Subjects in 36 CFR Part 67

Administrative practice and procedures, Historic preservation, Income taxes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the NPS proposes to amend 36 CFR part 67 as follows:

PART 67—HISTORIC PRESERVATION CERTIFICATIONS UNDER THE INTERNAL REVENUE CODE

1. The authority citation for part 67 is revised to read as follows:

Authority: 16 U.S.C. 470a(a)(1)(A); 26 U.S.C. 47 and 170(h).

2. In part 67, revise the heading to read as set forth above.

3. In part 67, remove the words “regional office” and “regional offices” wherever they occur and add in their place “WASO.”

4. In part 67, remove the words and numbers “Sec. 48(g)” wherever they occur and add in their place the words and numbers “Sec. 47.”

5. In part 67, remove the words and numbers “section 48(g)” wherever they occur and add in their place the words and numbers “section 47.”

6. In § 67.1,

A. Revise the section heading

B. Revise paragraph (a) and the first sentence of paragraph (b)

The revisions read as follows:

§ 67.1 Program authority and function.

(a) Section 47 of the Internal Revenue Code designates the Secretary as the authority for the issuance of certifications of historic district statutes and of State and local historic districts, certifications of significance, and certifications of rehabilitation in connection with certain tax incentives involving historic preservation. These certification responsibilities have been delegated to the National Park Service (NPS); the following office issues those certifications: National Park Service, Washington Area Service Office,

Technical Preservation Services, Heritage Preservation Services, (WASO), 1849 C Street, NW., Washington, DC 20240.

(b) NPS WASO establishes program direction and considers appeals of certification denials. * * *

* * * * *

7. In § 67.4, revise paragraph (g) to read as follows:

§ 67.4 Certifications of historic significance.

* * * * *

(g) For purposes of the other rehabilitation tax credits under sec. 47 of the Internal Revenue Code, properties within registered historic districts are presumed to contribute to the significance of such districts unless certified as nonsignificant by the Secretary. Owners of non-historic properties within registered historic districts, therefore, must obtain a certification of nonsignificance in order to qualify for those investment tax credits. If an owner begins or completes a substantial rehabilitation (as defined by the Internal Revenue Service) of a property in a registered historic district without knowledge of requirements for certification of nonsignificance, he or she may request certification that the property was not of historic significance to the district prior to substantial rehabilitation in the same manner as stated in § 67.4(c). The owner should be aware, however, that the taxpayer must certify to the Secretary of the Treasury that, at the beginning of such substantial rehabilitation, he or she in good faith was not aware of the certification requirement by the Secretary of the Interior.

* * * * *

8. In § 67.5 revise the section heading to read as follows:

§ 67.5 Standards for evaluating significance within registered historic districts.

* * * * *

9. In § 67.7 revise the section heading to read as follows:

§ 67.7 Standards for rehabilitation.

* * * * *

10. In § 67.10, revise paragraphs (a), (b), and (c)(3) to read as follows:

§ 67.10 Appeals.

(a) The owner or a duly authorized representative may appeal any of the certifications or denials of certification made under this part or any decisions made under § 67.6(f).

(1) Appeals must:

(i) Be in writing; e.g. letter, fax, or e-mail;

(ii) Be addressed to the Chief Appeals Officer, Cultural Resources, National Park Service, U.S. Department of the Interior, 1849 C Street, NW., Washington, DC 20240;

(iii) Be received by NPS within 30 days of receipt by the owner or a duly authorized representative of the decision which is the subject of the appeal; and

(iv) Include all information the owner wishes the Chief Appeals Officer to consider in deciding the appeal.

(2) The appellant may request a meeting to discuss the appeal.

(3) NPS will notify the SHPO that an appeal is pending.

(4) The Chief Appeals Officer will consider the record of the decision in question, any further written submissions by the owner, and other available information and will provide the appellant a written decision as promptly as circumstances permit.

(5) Appeals under this section constitute an administrative review of the decision appealed from and are not conducted as an adjudicative proceeding.

(b) The denial of a preliminary determination of significance for an individual property may not be appealed by the owner because the denial itself does not exhaust the administrative remedy that is available. The owner instead must seek recourse by undertaking the usual nomination process (36 CFR part 60).

(c) * * *

(3) Resubmit the matter to WASO for further consideration; or

* * * * *

11. Revise § 67.11 to read as follows:

§ 67.11 Fees for processing certification requests.

(a) Fees are charged for reviewing certification requests according to the schedule and instructions provided in public notices in the **Federal Register** by NPS.

(b) No payment should be made until requested by the NPS. A certification decision will not be issued on an application until the appropriate remittance is received.

(c) Fees are nonrefundable.

Dated: October 5, 2010.

Eileen Sobeck,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2010-25853 Filed 10-14-10; 8:45 am]

BILLING CODE 4310-70-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 10-1806; MB Docket No. 10-189; RM-11611]

Radio Broadcasting Services; Willow Creek, CA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document sets forth a proposal to amend the FM Table of Allotments. The Commission requests comment on a petition filed by Miriam Media, Inc., proposing the allotment of FM Channel 258A at Willow Creek, California. Petitioner, the auction winner and permittee of Channel 253A, Willow Creek, has submitted an application to specify operation of the station on Channel 254C1 at Loleta, California. Petitioner proposes the allotment of Channel 258A at Willow Creek in order to maintain a first local service at that community. Petitioner concedes that the signal contour of proposed Channel 258A at Willow Creek would not provide 70 dBU city-grade coverage to the entire Census Designated Place of Willow Creek, but argues that it has demonstrated substantial compliance with section 73.315(a) of the Commission's rules, and that the proposed allotment would serve the public interest. Channel 258A can be allotted at Willow Creek in compliance with the Commission's minimum distance separation requirements at 40-57-29 North Latitude and 123-42-23 West Longitude. *See SUPPLEMENTARY INFORMATION infra.*

DATES: The deadline for filing comments is November 18, 2010. Reply comments must be filed on or before December 3, 2010.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Evan Carb, Esq., Law Offices of Evan D. Carb, PLLC, 1140 Nineteenth Street, NW., Suite 600, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Deborah A. Dupont, Media Bureau (202) 418-7072.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making*, MB Docket No. 10-189, adopted September 24, 2010, and released September 27, 2010. The full text of this Commission decision is

available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, (800) 378-3160, or via the company's Web site, <http://www.bcpweb.com>. This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of

2002, Public Law 107-198, *see* 44 U.S.C. 3506 (c)(4).

The Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications

Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel 258A at Willow Creek.

Federal Communications Commission.

John A. Karousos,
Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2010-26061 Filed 10-14-10; 8:45 am]

BILLING CODE 6712-01-P

Notices

Federal Register

Vol. 75, No. 199

Friday, October 15, 2010

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2010-0033]

National Advisory Committee on Microbiological Criteria for Foods; Re-Establishment

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of re-chartering of Committee.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice is announcing the re-chartering of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) by the Secretary of Agriculture on September 24, 2010. The Committee is being renewed in cooperation with the Department of Health and Human Services (HHS). The establishment of the Committee was recommended by a 1985 report of the National Academy of Sciences Committee on Food Protection, Subcommittee on Microbiological Criteria, "An Evaluation of the Role of Microbiological Criteria for Foods." The current charter for the NACMCF is available for viewing on the NACMCF homepage at http://www.fsis.usda.gov/About_FSYS/NACMCF/index.asp.

At this time the charter is being changed to add one individual affiliated with a consumer group to be appointed to the NACMCF as a representative member. This member will provide a consumer viewpoint to Committee work and will not be required to have a scientific background. The balance of the Committee membership will be scientists, and those who are not regular government employees will be appointed as special government employees.

FOR FURTHER INFORMATION CONTACT:

Karen Thomas-Sharp, Advisory Committee Specialist, U.S. Department

of Agriculture (USDA), Food Safety and Inspection Service (FSIS), Room 333 Aerospace Center, 1400 & Independence Avenue, SW., Washington, DC 20250-3700. Telephone number: (202) 690-6620.

SUPPLEMENTARY INFORMATION:

Background

USDA is charged with administration and the enforcement of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). The Secretary of HHS is charged with the administration and enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA). These Acts help protect consumers by assuring that food products are wholesome, not adulterated, and properly marked, labeled and packaged.

In order to assist the Secretaries in carrying out their responsibilities under the FMIA, PPIA, EPIA, and FFDCA, the NACMCF is being re-chartered. The Committee will be charged with providing recommendations to the Secretaries on the development of microbiological criteria by which the safety and wholesomeness of food can be assessed, including criteria for microorganisms that indicate whether foods have been adequately and appropriately processed.

Re-chartering of this Committee is necessary and in the public interest because of the need for external expert advice on the range of scientific and technical issues that must be addressed by the Federal sponsors in meeting their statutory responsibilities. The complexity of the issues to be addressed requires that the Committee is expected to meet one or more times annually.

Members will be appointed by the Secretary of USDA after consultation with the Secretary of HHS. Because of their interest in the matters to be addressed by this Committee, advice on membership appointments will be requested from the Department of Commerce's National Marine Fisheries Service, the Department of Defense's Veterinary Service Activity, and the Department of Health and Human Services' Centers for Disease Control and Prevention. Background materials are available on the Web at the address noted above or by contacting Karen Thomas-Sharp.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at http://www.fsis.usda.gov/regulations/2010_Notices_Index/.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.

Options range from recalls, export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on October 12, 2010.

Alfred V. Almanza,
Administrator.

[FR Doc. 2010-26021 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2010-0016]

Availability of Compliance Guide for the Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a compliance guide on the use of video or other electronic monitoring or recording equipment in federally inspected establishments. FSIS has posted this compliance guide on its Significant Guidance Documents Web page (http://www.fsis.usda.gov/Significant_Guidance/index.asp). FSIS is publishing this as draft guidance while pursuing OMB approval of information collection under the Paperwork Reduction Act related to Hazard Analysis and Critical Control Point and Sanitation Standard Operating Procedures video records. FSIS is soliciting comments on this compliance guide. Once FSIS receives OMB approval on the information collection, it will reissue a final guide. At that time, FSIS may also make changes to the guide based on comments received on the draft guide.

DATES: Submit written comments by December 14, 2010.

ADDRESSES: FSIS invites interested persons to submit comments on this notice and the compliance guide. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, FSIS, Room 2-2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5272, Beltsville, MD 20705-5474.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2010-0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Isabel Arrington, U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), by phone at (402) 344-5000 or by e-mail at Isabel.Arrington@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

This compliance guide provides information to industry to help it maintain compliance with Federal regulations, including humane treatment of livestock and the use of good commercial practices in poultry. FSIS is providing this draft guide to advise establishments that video or other electronic monitoring or recording equipment can be used in federally inspected establishments. This guide informs establishments of the Agency's expectations if they decide to use this type of equipment to create records to meet the requirements of the Hazard Analysis and Critical Control Points regulations, or the regulations governing Sanitation Standard Operating Procedures. In addition, this guide provides information on issues establishments should consider if they use this equipment for any other purpose, such as part of their food defense plans.

FSIS is publishing this draft guide while pursuing OMB approval of information collection under the Paperwork Reduction Act related to Hazard Analysis and Critical Control Point and Sanitation Standard Operating Procedures video records. FSIS is requesting comments through a separate **Federal Register** document on this information collection. Until the Agency receives OMB approval for the information collection, the draft guide should not be viewed as authoritative.

Once FSIS receives OMB approval, it will issue a final guide. At that time, FSIS may also make changes to the guide based on comments received on the draft guide.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/2010_Notices_Index/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on September 15, 2010.

Alfred V. Almanza,
Administrator.

[FR Doc. 2010-26027 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Kootenai National Forest, Lincoln County, Montana; Grizzly Vegetation and Transportation Management Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare a supplemental environmental impact statement.

SUMMARY: The Kootenai National Forest will prepare a Supplemental Environmental Impact Statement (SEIS) for the Grizzly Vegetation and Transportation Management Project (Grizzly Project). The Grizzly Project includes vegetation management, fuels reduction, watershed rehabilitation activities, wildlife habitat improvement, and access management changes, including road decommissioning. The project is located in the Grizzly planning subunit on the Three Rivers Ranger District, Kootenai National Forest, Lincoln County, Montana, and northeast of Troy, Montana. The Notice of Availability of the Draft EIS for this project was published in the **Federal Register** (72 FR 31821) on June 8, 2007, and the notice of the Final EIS (74 FR 24006) on May 22, 2009. The Record of Decision was issued concurrently with the Final EIS. On June 29, 2010, the United States District Court for the District of Montana issued a sixty-nine page decision granting in part and denying in part cross motions for summary judgment in this case which alleged that the Forest Service's authorization of the Grizzly, Miller, and Little Beaver Projects on the Kootenai National Forest violated NEPA, NFMA, and the ESA. Plaintiffs generally alleged that in authorizing these Projects for vegetation management, fuels reduction, watershed restoration, timber harvest, and other purposes, the Forest Service failed to adequately evaluate their impact on the threatened Cabinet-Yaak grizzly bears which inhabit the area. Regarding the Grizzly Vegetation and Transportation Management Project the court found that (1) the agency's conclusion that the Project was consistent with the Kootenai Forest Plan violated NFMA because there was insufficient information in the record to determine whether the Projects complied with the standard for Management Situation 1 lands which require the agency to "favor the needs of the grizzly bear when grizzly habitat and other land use values compete"; and (2) the agency's failure to explain why it used the bear management unit instead of the Forest as the proper level for analysis of cumulative effects and its failure to disclose and discuss the problems with the "Wakkinen Study" regarding grizzly habitat standards violated NEPA's "hard look" requirement. The Court enjoined all three Projects and remanded them to the agency to address the defects identified in its decision. (09-160, D. Mont.). A

Supplemental EIS is being prepared for the Grizzly Vegetation and Transportation Management Project to address these disclosures in the grizzly bear analysis.

DATES: Under 40 CFR 1502.9(c)(4), there is no formal scoping period for this proposed action. The supplemental draft environmental impact statement is expected to be available for public review and comment in late November, 2010 and the environmental impact statement is expected in February, 2011.

ADDRESSES: The line officer responsible for this analysis is Cami Winslow, Acting District Ranger, Three Rivers Ranger District, 12385 U.S. Hwy 2, Troy, MT 59935.

FOR FURTHER INFORMATION CONTACT: Contact Kathy Mohar, Team Leader, Three Rivers Ranger District, at (406) 295-4693.

SUPPLEMENTARY INFORMATION: The Grizzly Project Area is approximately 18 air miles northeast of Troy, Montana, within all or portions of T34N, R32W-R33W, T35N, R32W-R33W, and T36N, R32W-R33W, Lincoln County, Montana.

The Grizzly Project Supplemental EIS will provide additional information and disclosures on the grizzly bear analysis in support of the Record of Decision issued in April 2009. More specifically, the Supplemental EIS will provide clarification and additional information on the following disclosures as requested by the District Court of Montana:

1. Why the Bear Management Unit is the appropriate scale of analysis for cumulative effects.
2. Further discussion on the limitations of Wakkinen and Kasworm (1997) utilized as the Best Available Science in regard to grizzly bear habitat protection in the Cabinet-Yaak Ecosystem Grizzly Bear Recovery Zone.
3. Further explanation on how the Grizzly Project was made compatible with grizzly bear needs, consistent with the Kootenai National Forest 1987 Forest Plan.

Record of Decision—Alternative 2a

The Grizzly Project Record of Decision issued in April 2009 authorized the following:

Vegetation treatments: Restoration of western white pine and western larch on 340 acres; restoration of low and moderate intensity fire regime vegetation characteristics on 548 acres; enhancement of aspen habitat on 19 acres; ecosystem and wildlife burning on 468 acres; precommercial thinning on 515 acres. These activities will

contribute an estimated 8.2 million board feet of forest products to markets.

Transportation actions: Placing 15.5 miles of road in intermittent stored service status to improve grizzly bear habitat; active decommissioning on 15.4 miles of unneeded road, and storage work on 9.7 miles of road to reduce sediment delivery prior to placing in grizzly bear core habitat; best management practices on 36 miles of road; passive decommissioning of 27 miles of road; designate 65.5 miles of currently open roads as open to motorized use; designate 39 miles of existing trails within grizzly bear habitat for non-motorized use. The proposed action and alternatives were originally described and analyzed in the FEIS, located at <http://www.fs.fed.us/r1/kootenai/projects/projects/Grizzly/index.shtml>. At this time no new alternatives are expected.

Supplemental Environmental Impact Statement

A Draft SEIS is expected to be available for public review and comment in late November 2010; and a Final SEIS in February 2011. The comment period for the Draft SEIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final supplemental environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft SEIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Responsible Official: Paul Bradford, Forest Supervisor of the Kootenai National Forest, 31374 US Hwy 2, Libby, MT 59923 is the Responsible Official for the Grizzly Project.

Dated: October 8, 2010.

Paul Bradford,

Forest Supervisor, Kootenai National Forest.

[FR Doc. 2010-25969 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

West Virginia Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The West Virginia Resource Advisory Committee will meet in Elkins, West Virginia. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose is for the committee to consider new project proposals.

DATES: The meeting will be held on October 29, 2010, and will begin at 10 a.m.

ADDRESSES: The meeting will be held at the Monongahela National Forest Supervisor's Office, 200 Sycamore Street, Elkins, WV 26241. Written comments should be sent to Kate Goodrich-Arling at the same address. Comments may also be sent via e-mail to kgoodricharling@fs.fed.us, or via facsimile to 304-637-0582.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241.

FOR FURTHER INFORMATION CONTACT: Kate Goodrich-Arling, RAC coordinator, USDA, Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241;

(304) 636-1800; e-mail kgoodricharling@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Review and approval or amendment of notes from previous meeting; (2) consider new project proposals; and (3) public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: September 29, 2010.

Clyde N. Thompson,

Designated Federal Officer.

[FR Doc. 2010-25940 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

Nevada and Placer Counties Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Nevada and Placer Counties Resource Advisory Committee (RAC) will meet in Auburn, California. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is to discuss projects submitted for funding and the expenditure of Title II funds benefiting National Forest System lands in Nevada and Placer Counties.

ADDRESSES: The meeting will be held at the Placer County Water Agency office, 144 Ferguson, Rd., Auburn, CA.

FOR FURTHER INFORMATION CONTACT: Ann Westling, Committee Coordinator, USDA, Tahoe National Forest, 631 Coyote St., Nevada City, CA 95959, (530) 478-6205, e-mail: awestling@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Welcome and Introductions; (2) Review of RAC Operating Guidelines; (3)

Discussion of Proposed Projects; (4) Vote on Proposed Projects; and (5) Comments from the Public. The meeting is open to the public and the public will have an opportunity to comment at the meeting.

Dated: October 5, 2010.

Tom Quinn,

Forest Supervisor.

[FR Doc. 2010-25995 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Glenn/Colusa County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn/Colusa County Resource Advisory Committee (RAC) will meet in Willows, California. Agenda items covered include: (1) Introductions, (2) Approve Minutes, (3) RAC Admin Updates, (4) Public Comment, (5) Project Updates FY 08, 09, 10, (6) General Discussion, (9) Meeting Schedule, (8) Adjourn.

DATES: The meeting will be held on October 18, 2010, from 1:30 p.m. and end at approximately 4:30 p.m.

ADDRESSES: The meeting will be held at the Mendocino National Forest, Grindstone Ranger District Office, 825 N. Humboldt Ave., Willows, CA 95988. Individuals who wish to speak or propose agenda items send their names and proposals to Eduardo Olmedo, DFO, 825 N. Humboldt Ave., Willows, CA 95988 or Laurie Trombley, Glenn/Colusa RAC Coordinator, USDA, Mendocino National Forest, Grindstone Ranger District, P.O. Box 160, Stonyford, CA 95979.

FOR FURTHER INFORMATION CONTACT: Laurie Trombley, Glenn/Colusa RAC Coordinator, USDA, Mendocino National Forest, Grindstone Ranger District, P.O. Box 160, Stonyford, CA 95979, (530) 963-3128 E-Mail: ltrombley@fs.fed.us. Eduardo Olmedo, District Ranger, USDA, Mendocino National Forest, Grindstone Ranger District, 825 N. Humboldt St., Willows, CA 95988, (530) 934-3316 E-mail: eolmedo@fs.fed.us.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Committee discussion is limited to Forest Service staff and Committee members. However, persons who wish to bring matters to the attention of the Committee will file written statements with the Committee staff before or after

the meeting. Public input sessions are provided and individuals who made written requests by May 17, 2010 have the opportunity to address the committee at those sessions.

Dated: October 6, 2010.

Eduardo Olmedo,

Designated Federal Official, Glenn/Colusa County RAC Meeting Agenda.

[FR Doc. 2010-26010 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Del Norte Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Del Norte Resource Advisory Committee (RAC) will meet in Crescent City, California. The committee meeting is authorized under the Secure Rural Schools and Community Self-Determination (SRS) Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act.

DATES: The meeting will be held November 9, 2010, from 5 p.m. to 9 p.m.

ADDRESSES: The meeting will be held at the Del Norte County Unified School District, Redwood Room, 301 West Washington Boulevard, Crescent City, California 95531.

FOR FURTHER INFORMATION CONTACT: Julie Ranieri, Committee Coordinator, Six Rivers National Forest, at (707) 441-3673; e-mail: jranieri@fs.fed.us.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The purpose of this meeting is to vote on which projects the RAC will recommend for funding. Public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: October 8, 2010.

Tyrone Kelley,

Forest Supervisor.

[FR Doc. 2010-25970 Filed 10-14-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator of the Foreign Agricultural Service (FAS) has denied a petition (No. 2011032) for trade adjustment assistance (TAA) for blueberries filed under the fiscal year (FY) 2011 program by three producers on behalf of blueberry producers in New Hampshire. The petition was accepted for review by USDA on August 13, 2010.

SUPPLEMENTARY INFORMATION: To qualify under the program, Subtitle C of Title I of the Trade Act of 2002 (Pub. L. 107-210) states that petitions must demonstrate, using data for the most recent, full marketing year or full official marketing season, a greater than 15-percent decline in at least one of the following factors: national average price, quantity of production, value of production, or cash receipts.

According to the statute, it is also necessary for the petition to demonstrate that an increase in imports of like or directly competitive articles, during the same marketing period, contributed importantly to the decrease in one of the above factors for the agricultural commodity.

All petitions were analyzed by USDA's Economic Research Service and reviewed by the TAA for Farmers Program Review Committee, comprised of representatives from USDA's Office of the Chief Economist, Farm Service Agency, Agricultural Marketing Service, and FAS. After a review, the Administrator determined that the petition was unable to demonstrate the 'greater than 15-percent decline' criterion, because it showed a 26.4-percent increase in production quantity for 2009, instead of the required decrease, when compared to the previous 3-year period.

Because the petition was unable to meet the 'greater than 15-percent decline' criterion, the Administrator was not able to certify it, making blueberry producers in New Hampshire ineligible for trade adjustment assistance in FY 2011.

FOR FURTHER INFORMATION CONTACT:

Trade Adjustment Assistance for Farmers Program Staff, Office of Trade Programs, FAS, USDA, at (202) 720-0638, or (202) 690-0633, or by e-mail at: tradeadjustment@fas.usda.gov, or visit the TAA for Farmers' Web site at: <http://www.fas.usda.gov/itp/taa>.

Dated: October 6, 2010.

Susanne Hale,

Acting Administrator, Foreign Agricultural Service.

[FR Doc. 2010-26008 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-10-P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator of the Foreign Agricultural Service (FAS) has denied a petition (No. 2011016) for trade adjustment assistance (TAA) for northeast multi-species fish filed under the fiscal year (FY) 2011 program by the New Hampshire Commercial Fisherman's Association. The petition was accepted for review by USDA on August 16, 2010.

SUPPLEMENTARY INFORMATION: To qualify under the program, Subtitle C of Title I of the Trade Act of 2002 (Pub. L. 107-210) states that petitions must demonstrate, using data for the most recent full marketing year or full official marketing season, a greater than 15-percent decline in at least one of the following factors: National average price, quantity of production, value of production, or cash receipts.

According to the statute, it is also necessary for the petition to demonstrate that an increase in imports of like or directly competitive articles, during the same marketing period, contributed importantly to the decrease in one of the above factors for the agricultural commodity.

All petitions were analyzed by USDA's Economic Research Service and reviewed by the TAA for Farmers Program Review Committee, comprised of representatives from USDA's Office of the Chief Economist, Farm Service Agency, Agricultural Marketing Service, and FAS. After a review, the Administrator determined that the petition was able to demonstrate the "greater than 15-percent decline" criterion, because it showed a 17-percent decline in the average annual price for 2009, when compared to the previous 3-year period. However, the import data provided for the same time period showed a 5.8-percent decrease, instead of the required increase, under the program.

Because the petition was unable to meet the "increase in imports" criterion, the Administrator was not able to certify the petition, making northeast multi-species fish producers in Connecticut, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, and Rhode Island ineligible for trade adjustment assistance in FY 2011.

FOR FURTHER INFORMATION CONTACT:

Trade Adjustment Assistance for Farmers Program Staff, Office of Trade Programs, FAS, USDA, at (202) 720-0638, or (202) 690-0633, or by e-mail at: tradeadjustment@fas.usda.gov, or visit the TAA for Farmers' Web site at: <http://www.fas.usda.gov/itp/taa>.

Dated: October 6, 2010.

Suzanne Hale,

Acting Administrator, Foreign Agricultural Service.

[FR Doc. 2010-26011 Filed 10-14-10; 8:45 am]

BILLING CODE 3410-10-P

DEPARTMENT OF COMMERCE**Submission for OMB Review; Comment Request**

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Statement of Financial Interests, Regional Fishery Management Councils.

OMB Control Number: 0648-0192.

Form Number(s): 88-195.

Type of Request: Regular submission (extension of an existing information collection).

Number of Respondents: 330.

Average Hours per Response: 35 minutes.

Burden Hours: 193.

Needs and Uses: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson Stevens Act) authorizes the establishment of Regional Fishery Management Councils to exercise sound judgment in the stewardship of fishery resources through the preparation, monitoring, and revision of such fishery management plans under circumstances (a) which will enable the States, the fishing industry, consumers, environmental organizations, and other interested persons to participate in the development of such plans, and (b) which take into account the social and economic needs of fishermen and dependent communities.

Section 302(j) of the Magnuson-Stevens Act requires that Council members appointed by the Secretary, Scientific and Statistical Committee (SSC) members appointed by a Council under Section 302(g)(1), or individuals nominated by the Governor of a State for possible appointment as a Council member, disclose their financial interest

in any Council fishery. These interests include harvesting, processing, lobbying, advocacy, or marketing activity that is being, or will be, undertaken within any fishery over which the Council concerned has jurisdiction, or with respect to an individual or organization with a financial interest in such activity. Seated Council members appointed by the Secretary, including the Tribal Government appointee and SSC members, must file a financial interest form within 45 days of taking office and must provide an update of their statements at any time any such financial interest is acquired, or substantially changed.

Affected Public: Individuals or households.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer:

OIRA_Submission@omb.eop.gov.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

OIRA_Submission@omb.eop.gov.

Dated: October 12, 2010.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010-25985 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**Submission for OMB Review; Comment Request**

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Conflict of Interest Disclosure for Nonfederal Government Individuals Who Are Candidates To Conduct Peer Reviews.

OMB Control Number: 0648-0567.

Form Number(s): NA.

Type of Request: Regular submission (renewal of a currently approved information collection).

Number of Respondents: 320.

Average Hours per Response: 30 minutes.

Burden Hours: 160.

Needs and Uses: The Office of Management and Budget's Final Information Quality Bulletin for Peer Review ("Peer Review Bulletin" or PRB) establishes minimum peer review standards for influential scientific information that Federal agencies intend to disseminate. The PRB also directs federal agencies to adopt or adapt the National Academy of Sciences (NAS) policy for evaluating conflicts of interest when selecting peer reviewers who are not Federal government employees (Federal employees are subject to Federal ethics requirements which address conflict of interest). For peer review purposes, the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it could: (1) Significantly impair the individual's objectivity; or (2) create an unfair competitive advantage for any person or organization.

NOAA has adapted the NAS policy and developed three confidential conflict of interest disclosure forms which will be used to examine prospective reviewers' potential financial conflicts and other interests that could impair objectivity or create an unfair advantage. The forms are for peer reviewers of studies related to government regulation; peer reviewers of any other influential scientific information subject to the Peer Review Bulletin; and potential reviewers of scientific laboratories. The forms include questions about employment as well as investment and property interests, and research funding. All three forms also require the submission of a curriculum vitae.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer:

OIRA_Submission@omb.eop.gov.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to
OIRA_Submission@omb.eop.gov.

Dated: October 12, 2010.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010-25986 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; NOAA Teacher at Sea Alumni Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before December 14, 2010.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jennifer Hammond, (301) 713-1364 or Jennifer.Hammond@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a renewal of a currently approved information collection. The National Oceanic and Atmospheric Administration (NOAA) provides educators an opportunity to gain first-hand experience with field research activities through the Teacher at Sea Program. Through this program, educators spend up to three weeks at sea on a NOAA research vessel, participating in an on-going research project with NOAA scientists. Once educators are selected and participate on a cruise, they write a report detailing the events of the cruise and ideas for

classroom activities based on what they learned while at sea. These materials are then made available to other educators so they may benefit from the experience, without actually going to sea themselves. In order to better serve the participants, the Teacher at Sea Program will survey the teacher participants on their experience before, during, and after they return from sea. The survey will collect data only from teacher participants, not from applicants.

II. Method of Collection

Forms can be completed on line, printed, and mailed. Persons with full Adobe Acrobat software can save the on-line form and submit it electronically.

III. Data

OMB Control Number: 0648-0600.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 375.

Estimated Time per Response: 1 hour to read and complete survey, and 1 hour for a follow-up call from the external evaluator.

Estimated Total Annual Burden Hours: 750.

Estimated Total Annual Cost to Public: \$0.

IV. Request for Comments

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 (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 12, 2010.

Gwellnar Banks,

Management Analyst, Office of Chief Information Officer.

[FR Doc. 2010-25992 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-502]

Certain Welded Carbon Steel Standard Pipes and Tubes From India: Extension of the Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Michael A. Romani or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone (202) 482-0198 or (202) 482-1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 14, 2010, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain welded carbon steel standard pipes and tubes from India. *See Certain Welded Carbon Steel Standard Pipes and Tubes from India: Preliminary Results of Antidumping Duty Administrative Review*, 75 FR 33578 (June 14, 2010). The review covers the period May 1, 2008, through April 30, 2009. The final results of the review are currently due no later than October 12, 2010.

Extension of Time Limit for Final Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the final results of an administrative review within 120 days after the date on which the preliminary results are published. If it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the final results up to 180 days after the date on which the preliminary results are published.

We determine that it is not practicable to complete the final results of this review within the original time limit because we need additional time to analyze certain complicated issues relating to the universe of sales and the date of sale. Therefore, we are extending the time period for issuing the final results of this review by 24 days until November 5, 2010.

This notice is published in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: October 7, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-26060 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-890]

Wooden Bedroom Furniture From the People's Republic of China: Correction to Notice of Extension of Preliminary Results of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Jeffrey Pedersen or Rebecca Pandolph, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-2769 or (202) 482-3627, respectively.

Correction

On August 27, 2010, the Department of Commerce (the Department) published a notice of extension of time limit for the preliminary results of the antidumping new shipper review of wooden bedroom furniture from the People's Republic of China for the period January 1, 2009, through December 31, 2009. *See Wooden Bedroom Furniture From the People's Republic of China: Extension of Preliminary Results of Antidumping Duty New Shipper Review*, 75 FR 52716 (August 27, 2010) (Extension Notice). Subsequent to the publication of the Extension Notice, we identified an inadvertent clerical error in the Extension Notice.

Under the "Extension of Time Limits for Preliminary Results" section of the Extension Notice, the Department discussed the reasons for extending the preliminary results of the new shipper review but then incorrectly stated that it was "extending the time for the completion of the final results" and noted that "the deadline for completion of the final results of these reviews is now no later than December 27, 2010." The purpose of the instant notice is to

notify parties of the error and to correct the error.

The Department has not extended the final results of the new shipper review. Rather, the Extension Notice was meant to extend the preliminary results of the new shipper review. Thus, the preliminary results of the new shipper review are due no later than December 27, 2010.

This correction notice is issued and published in accordance with sections 751(a)(2)(B)(iv) and 751(h) of the Act.

Dated: October 7, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-26069 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-832]

Pure Magnesium From the People's Republic of China: Extension of Time for the Final Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4243.

Background

On June 18, 2010, the Department of Commerce ("the Department") published the preliminary results of this administrative review for the period May 1, 2008, to April 30, 2009. *See Pure Magnesium from the People's Republic of China: Preliminary Results of the 2008-2009 Antidumping Duty Administrative Review*, 75 FR 34689 (June 18, 2010). The final results of review are currently due on October 18, 2010.

Extension of Time Limits for the Final Results of Review

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended ("the Act"), requires the Department to issue final results within 120 days after the date on which the preliminary results are published. However, if it is not

practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend the time period to a maximum of 180 days. Completion of the final results of the administrative review within the 120-day period is not practicable because the Department requires additional time to analyze information obtained at verification, evaluate the surrogate value information placed on the record, and consider the arguments raised by the parties in the case and rebuttal briefs and provided at the hearing.

Because it is not practicable to complete this review within the time specified under the Act, we are extending the time period for issuing the final results of the administrative review to 180 days, until December 15, 2010, in accordance with section 751(a)(3)(A) of the Act.

We are publishing this notice pursuant to sections 751(a) and 777(i) of the Act.

Dated: October 7, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-26067 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-851]

Certain Preserved Mushrooms From the People's Republic of China; Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Scott Hoefke or Fred Baker, AD/CVD Operations Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-4947 or (202) 482-2924, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 30, 2010, the Department of Commerce (the Department) published in the **Federal Register** the initiation of administrative review of the antidumping duty order on certain preserved mushrooms from the People's

Republic of China, covering the period of February 1, 2009, through January 31, 2010. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 75 FR 15679 (March 30, 2010). The current deadline for the preliminary results of this review is October 31, 2010.

Extension of Time Limits for Preliminary Results of Review

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires that the Department complete the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested. However, if it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month of an order for which a review is requested.

The Department finds that it is not practicable to complete the preliminary results of this review within the original time frame because comments from interested parties have necessitated the solicitation and subsequent analysis of additional information from all respondents: Xiamen International Trade & Industrial Co., Ltd.; Guangxi Jisheng Foods, Inc.; and Blue Field (Sichuan) Food Industrial Co., Ltd. This additional information covers a wide range of issues and is extensive. The Department requires additional time to gather and analyze the additional information. Thus, the Department finds it is not practicable to complete this review within the original time limit (*i.e.*, October 31, 2010). Accordingly, the Department is extending the time limit for completion of the preliminary results of this administrative review by 120 days (*i.e.*, until February 28, 2011), in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2). We intend to issue the final results no later than 120 days after publication of the preliminary results notice.

This extension is issued and published in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: October 7, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-26093 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability for Public Comment on the Interagency Ocean Observation; Committee Proposed Certification Design Process

AGENCY: National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce (DOC).

ACTION: Notice of availability; request for comments.

SUMMARY: The NOAA Integrated Ocean Observing System (IOOS) Program publishes this notice on behalf of the Interagency Ocean Observation Committee (IOOC) to announce a 60-day public comment period for the proposed certification design process mandated by the Integrated Coastal and Ocean Observation System Act of 2009 (ICOOS Act). The IOOC will use the proposed process to develop certification standards for non-federal assets, including regional information coordination entities, to establish eligibility for integration into the Integrated Ocean Observing System (System).

DATES: Written, faxed or e-mailed comments must be received no later than 5 p.m. eastern standard time on November 15, 2010.

ADDRESSES: The IOOC proposed certification design process and additional background material is available for review from the IOOC Web site URL: <http://www.iooc.us> or the IOOS Program Web site URL: <http://www.ioos.gov>. For the public unable to access the Internet, printed copies can be requested by contacting the IOOC Support Office at the address below. The public is encouraged to submit comments electronically to certification@iooc.us. If you are unable to access the Internet, comments may be submitted via fax or regular mail. Faxed comments should be sent to 202-332-8887 with *Attn:* IOOC Support Office. Comments may be submitted in writing to the Consortium for Ocean Leadership, *Attention:* IOOC Support Office, 1201 New York Avenue, NW., 4th Floor, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For further information about this notice, please contact the IOOC Support Office, telephone: 202-787-1622; *E-mail:* certification@iooc.us or the IOOS Program Office, telephone 301-427-2442.

SUPPLEMENTARY INFORMATION: On 30 March 2009, President Barack Obama signed into law the Integrated Coastal and Ocean Observation System Act of 2009. Among the requirements in the Act is a directive to the IOOC to develop contract certification standards and compliance procedures for all non-Federal assets, including regional information coordination entities, to establish eligibility for integration into the System and to ensure compliance with all applicable standards and protocols established and to ensure that regional observations are integrated into the System on a sustained basis. The IOOC seeks public comment on both the proposed process to create these standards and on the scope and structure of the standards. The proposed certification design process and additional background information are available on the IOOC and IOOS Web sites or by contacting the IOOC Support Office or the IOOS Program Office. The IOOC is the Federal interagency group established in accordance with the ICOOS Act to lead the interagency planning and coordination of ocean observing activities including IOOS. The IOOC is comprised of representatives of eleven Federal agencies. The ICOOS Act identifies NOAA as the lead Federal agency. As defined in the IOOC charter, the purpose of the IOOC is to advise and assist national ocean governance bodies like the Ocean Science and Technology Interagency Policy Committee, called for in the National Ocean Policy, on matters relating to a national, end-to-end ocean observing system.

Dated: October 5, 2010.

David M. Kennedy,

Acting Assistant Administrator for Ocean Service and Coastal Zone Management.

[FR Doc. 2010-26003 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XZ68

Pacific Fishery Management Council (Pacific Council); November 3-9, 2010, Pacific Council Meeting

AGENCY: NMFS, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Council and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet November 3–9, 2010. The Pacific Council meeting will begin on Thursday, November 4, 2010 at 9:30 a.m., reconvening each day through Tuesday, November 9, 2010. All meetings are open to the public, except a closed session will be held from 9:30 a.m. until 10:30 a.m. on Thursday, November 4 to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: Meetings of the Pacific Council and its advisory entities will be held at the Hilton Orange County Costa Mesa Hotel, 3050 Bristol Street, Costa Mesa, California 92626; telephone: 714–540–7000. The Pacific Council address is Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, Oregon 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. McIsaac, Executive Director; telephone: 503–820–2280 or 866–806–7204 toll free; or access the Pacific Council Web site, <http://www.pcouncil.org> for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the Pacific Council agenda, but not necessarily in this order:

- A. Call to Order
 - 1. Opening Remarks and Introductions
 - 2. Roll Call
 - 3. Executive Director's Report
 - 4. Approve Agenda
- B. Open Comment Period
 - 1. Comments on Non-Agenda Items
- C. Enforcement Issues
 - 1. Washington Department of Fish and Wildlife Enforcement Report
- D. Ecosystem Based Management
 - 1. Ecosystem Science Information Session
- E. Habitat
 - 1. Current Habitat Issues
 - 2. Deepwater Coral Information Report
- F. Salmon Management
 - 1. Preseason Salmon Management Schedule for 2011
 - 2. Fishery Management Plan Amendment 16, Annual Catch Limits and Accountability Measures
 - 3. Progress Report on Sacramento River Fall Chinook Overfishing Assessment
 - 4. Mitchell Act Hatchery Draft Environmental Impact Statement
 - 5. 2010 Salmon Methodology Review
- G. Pacific Halibut Management
 - 1. 2011 Pacific Halibut Regulations
- H. Groundfish Management
 - 1. Initial Consideration of Revisions to

- the Groundfish Biennial Management Process
- 2. National Marine Fisheries Service Report
- 3. Consideration of Inseason Adjustments—Part I
- 4. Final Review of Exempted Fishing Permits for 2011
- 5. Implementation Update for Amendment 20 (Trawl Rationalization) and Amendment 21 (Intersector Allocation) as well as Scoping of Prioritized Trailing Amendments
- 6. Consideration of Inseason Adjustments—Part II, if Necessary
- I. Coastal Pelagic Species Management
 - 1. National Marine Fisheries Service Report
 - 2. Pacific Sardine Stock Assessment and Coastal Pelagic Species Management Measures for 2011
 - 3. Terms of Reference for Stock Assessment and Methodology Review Panels
 - 4. Coastal Pelagic Species Essential Fish Habitat Five Year Review
- J. Highly Migratory Species Management
 - 1. National Marine Fisheries Service Report
 - 2. Changes to Biennial Management Measures for 2011–2012
 - 3. Recommendations to International Fishery Management Organizations
- K. Administrative Matters
 - 1. Approval of Council Meeting Minutes
 - 2. Fiscal Matters
 - 3. Membership Appointments, Council Operating Procedures, and Miscellaneous Administrative Matters
 - 4. Future Council Meeting Agenda and Workload Planning

Schedule of Ancillary Meetings

- Day 1—Wednesday, November 3, 2010
 - Habitat Committee—8 a.m.
 - Salmon Advisory Subpanel—8 a.m.
 - Salmon Technical Team and Salmon Amendment Committee Joint Session—8 a.m.
 - Scientific and Statistical Committee—8 a.m.
 - Ad Hoc Mitchell Act Committee—8:30 a.m.
 - Budget Committee—3:30 p.m.
 - Annual Awards Banquet—6 p.m.
- Day 2—Thursday, November 4, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Groundfish Advisory Subpanel—8 a.m.
 - Habitat Committee—8 a.m.
 - Salmon Advisory Subpanel—8 a.m.
 - Salmon Technical Team and Salmon Amendment Committee Joint

- Session—8 a.m.
 - Scientific and Statistical Committee—8 a.m.
 - Groundfish Management Team—2 p.m.
 - Enforcement Consultants—4:30 p.m.
 - Day 3—Friday, November 5, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Coastal Pelagic Species Advisory Subpanel—8 a.m.
 - Coastal Pelagic Species Management Team—8 a.m.
 - Groundfish Advisory Subpanel—8 a.m.
 - Groundfish Management Team—8 a.m.
 - Enforcement Consultants—As Necessary
 - Day 4—Saturday, November 6, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Coastal Pelagic Species Advisory Subpanel—8 a.m.
 - Coastal Pelagic Species Management Team—8 a.m.
 - Groundfish Advisory Subpanel—8 a.m.
 - Groundfish Management Team—8 a.m.
 - Enforcement Consultants—As Necessary
 - Day 5—Sunday, November 7, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Groundfish Advisory Subpanel—8 a.m.
 - Groundfish Management Team—8 a.m.
 - Highly Migratory Species Advisory Subpanel—8 a.m.
 - Highly Migratory Species Management Team—8 a.m.
 - Enforcement Consultants—As Necessary
 - Day 6—Monday, November 8, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Groundfish Advisory Subpanel—8 a.m.
 - Groundfish Management Team—8 a.m.
 - Highly Migratory Species Advisory Subpanel—8 a.m.
 - Highly Migratory Species Management Team—8 a.m.
 - Enforcement Consultants—As Necessary
 - Day 7—Tuesday, November 9, 2010
 - California State Delegation—7 a.m.
 - Oregon State Delegation—7 a.m.
 - Washington State Delegation—7 a.m.
 - Enforcement Consultants—As Necessary
- Although non-emergency issues not contained in this agenda may come

before this Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Carolyn Porter at 503-820-2280 at least five days prior to the meeting date.

Dated: October 12, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010-25979 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Protected Areas Federal Advisory Committee; Public Meeting

AGENCY: National Ocean Service, NOAA, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the Marine Protected Areas Federal Advisory Committee (Committee) in Santa Barbara, California.

DATES: The meeting will be held Tuesday, November 2, 2010, from 8:30 a.m. to 5:30 p.m., and Wednesday, November 3, from 8:30 a.m. to 5 p.m. These times and the agenda topics described below are subject to change. Refer to the Web page listed below for the most up-to-date meeting agenda.

ADDRESSES: The meeting will be held at Fess Parker's Doubletree Resort, 633 East Cabrillo Blvd., Santa Barbara, California.

FOR FURTHER INFORMATION CONTACT: Kara Schwenke, Designated Federal Officer, MPA FAC, National Marine Protected Areas Center, 1305 East West Highway, Silver Spring, Maryland 20910. (Phone: 301-713-3100 x162, Fax: 301-713-3110); e-mail: kara.schwenke@noaa.gov; or visit the National MPA Center Web site at <http://www.mpa.gov>.

SUPPLEMENTARY INFORMATION: The Committee, composed of external, knowledgeable representatives of stakeholder groups, was established by the Department of Commerce (DOC) to provide advice to the Secretaries of Commerce and the Interior on implementation of Section 4 of Executive Order 13158, which calls for the development of a National System of MPAs. The National System aims to strengthen existing MPAs and MPA programs through national and regional coordination, capacity building, science and analysis. The meeting will be open to public participation from 4:30 p.m. to 5:30 p.m. on Tuesday, November 2, 2010. In general, each individual or group will be limited to a total time of five (5) minutes. If members of the public wish to submit written statements, they should be submitted to the Designated Federal Official by October 28, 2010.

Matters to be Considered: The focus of the Committee's meeting will be the development of draft recommendations by the Subcommittees (Coastal and Marine Spatial Planning and Communities and Land/Sea Interactions) and the Cultural Heritage Workgroup for deliberation and action by the full MPA FAC. The Committee will hear from an expert speaker on the Integrated Ocean Observing System (IOOS), and how MPAs could be used as platforms for ocean monitoring. The Committee will hear from two panels of MPA experts: One on how MPAs can help support healthy and resilient coastal communities coastal communities, and one on how MPAs and the national system of MPAs relate to the National Ocean Policy and Coastal and Marine Spatial Planning Initiatives. The agenda is subject to change. The latest version will be posted at <http://www.mpa.gov>.

Dated: October 6, 2010.

Donna Wieting,

Director, Office of Ocean and Coastal Resource Management.

[FR Doc. 2010-26002 Filed 10-14-10; 8:45 am]

BILLING CODE M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Prospective Grant of Exclusive Patent License

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology ("NIST"), U.S. Department of Commerce, is contemplating the grant of an exclusive license in the United States of America, its territories, possessions and commonwealths, to NIST's interest in the invention embodied in U.S. Patent Application No. 12/820,218, titled "Magnetic Connectors For Microfluidic Applications," NIST Docket No. 09-020 to SFC Fluidics, LLC, having a place of business at 534 W. Research Center Blvd. Suite 260, Fayetteville, AR 72701. The grant of the license would be for the field of use: Magnetic Connectors For Microfluidic Applications.

FOR FURTHER INFORMATION CONTACT: J. Terry Lynch, National Institute of Standards and Technology, Technology Partnerships Office, 100 Bureau Drive, Stop 2200, Gaithersburg, MD 20899, Phone 301-975-2691.

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent Application No. 12/820,218 is owned by the U.S. government, as represented by the Secretary of Commerce. The invention comprises a first magnetic connector with at least one orifice extending therethrough and a second magnetic connector. The first and second connectors are configured to magnetically attract each other. In one aspect, the first magnetic connector is configured to sealingly engage a surface of a microfluidic chip with the second magnetic connector disposed on an opposite side of the microfluidic chip. The first magnetic connector is configured to seal with the microfluidic chip about a channel opening in the microfluidic chip and provide flow communication between the channel opening and the orifice in the first magnetic connector. In at least one other aspect, the first magnetic connector and second magnetic connector each have at least one orifice and are configured to change a flow communication there between upon a rotation of the first or

second magnetic connector with respect to the other magnetic connector.

Harry S. Hertz.

Director, Baldridge Performance Excellence Program.

[FR Doc. 2010-26072 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-836]

Glycine From the People's Republic of China: Notice of Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On April 27, 2010, the U.S. Department of Commerce (the Department) published a notice of initiation of an administrative review of the antidumping duty order on glycine from the People's Republic of China (PRC). The review covers 32 producers/exporters of glycine from the PRC. We are now rescinding this administrative review in full.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Dena Crossland or Brian Davis, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-3362 or (202) 482-7924, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2010, the Department published in the **Federal Register** the notice of opportunity to request an administrative review of the antidumping duty order on, *inter alia*, glycine from the PRC for the period March 1, 2009, through February 28, 2010. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 75 FR 9162 (March 1, 2010). On March 31, 2010, the Department received a timely request from GEO Specialty Chemicals, Inc. (GEO), a domestic producer of glycine, that the Department conduct an administrative review of the antidumping duty order on glycine from the PRC, covering 32 producers/exporters of glycine from the PRC. On April 27, 2010, the Department published in the **Federal Register** the notice of initiation of, *inter alia*, the

2009-2010 administrative review of glycine from the PRC. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 75 FR 22107 (April 27, 2010) (*Initiation*).

On April 30, 2010, GEO submitted comments regarding the Department's respondent selection process. On May 10, 2010, we received a letter from Paras Intermediates Private Limited (Paras) informing the Department that it is an Indian company that had no exports, sales, or entries of PRC glycine to the United States during the POR.¹ On May 20, 2010, the Department issued a memorandum providing an opportunity for interested parties to comment on United States Customs and Border Protection (CBP) information to be used by the Department in respondent selection. On May 24, 2010, Baoding Mantong Fine Chemistry Co., Ltd. (Baoding Mantong)² submitted a letter and certification to the Department advising the Department that Baoding Mantong "did not sell, ship, or export to the United States glycine subject to the above referenced antidumping duty order during the POR." On May 26, 2010, the Department issued a letter to Baoding Mantong requesting that it refile its statement of no shipments and to certify, if appropriate, that it had no exports, sales, or entries of subject merchandise during the POR.³ On May 28, 2010, we received a properly filed letter from Baoding Mantong stating that it did not sell, ship, or export, to the United States, subject merchandise during the POR. On July 30, 2010, GEO filed a letter withdrawing its request for

¹ Paras is one of the 32 companies named by GEO in its March 31, 2010, letter to the Department. In its March 31, 2010, letter to the Department, Paras also stated that all of Paras' exports of glycine to the United States are manufactured by Paras, in India, from monochloro acetic acid and ammonia.

² Baoding Mantong is also one of the 32 companies named by GEO in its March 31, 2010, letter to the Department.

³ The Department notes that the *Initiation Notice* states "{u}nder 19 CFR 351.213(d)(3), the Department may rescind a review where there are no exports, sales, or entries of subject merchandise during the respective period of review ('POR') listed below. If a producer or exporter named in this initiation notice had no exports, sales, or entries during the POR, it should notify the Department within 30 days of publication of this notice in the **Federal Register**. The Department will consider rescinding the review only if the producer or exporter, as appropriate, submits a properly filed and timely statement certifying that it had no exports, sales, or entries of subject merchandise during the POR." See 75 FR at 22107 (emphasis added). The Department found that Baoding Mantong did not properly file its statement that it had no exports, sales, or entries of subject merchandise during the POR in its original certification (May, 24, 2010, letter to the Department).

review of the 32 companies for which the Department initiated this review.

Period of Review

The period of review (POR) is March 1, 2009, through February 28, 2010.

Scope of the Order

The product covered by the order is glycine, which is a free-flowing crystalline material, like salt or sugar. Glycine is produced at varying levels of purity and is used as a sweetener/taste enhancer, a buffering agent, reabsorbable amino acid, chemical intermediate, and a metal complexing agent. This review covers glycine of all purity levels. Glycine is currently classified under subheading 2922.49.4020 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and Customs purposes, the written description of the merchandise subject to the order is dispositive.

Rescission of Antidumping Duty Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review under this section, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review, or withdraws at a later date if the Department determines it is reasonable to extend the time limit for withdrawing the request. GEO withdrew its review request after the 90-day deadline. However, the Department finds it reasonable to extend the withdrawal deadline for GEO because the Department has not yet devoted significant time or resources to this review. As a result, in accordance with 19 CFR 351.213(d)(1), the Department is rescinding the administrative review of all 32 companies.

Assessment Instructions

The Department will instruct CBP to assess antidumping duties on all appropriate entries. For companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: October 7, 2010.

Susan H. Kuhbach,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010-26087 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****Foreign-Trade Zone 86—Tacoma, WA; Site Renumbering Notice**

Foreign-Trade Zone 86 was approved by the Foreign-Trade Zones Board on July 20, 1983 (Board Order 216), expanded on April 3, 1985 (Board Order 292), November 3, 1989 (Board Order 446), and November 2, 2000 (Board Order 1131).

FTZ 86 currently consists of 12 "Sites" totaling 2,266 acres in the Tacoma, Washington area. The current update does not alter the physical boundaries that have previously been approved, but instead involves an administrative renumbering of the existing sites to separate unrelated, non-contiguous sites for record-keeping purposes.

Under this revision, the site list for FTZ 86 will be as follows: *Site 1* (621 acres)—Port of Tacoma Complex,

Tacoma; *Site 2* (137 acres)—Valley South Corporate Park, 142nd Avenue East, Sumner; *Site 3* (226 acres)—Port of Tacoma parcels, Frederickson, 19315 38th Avenue East and 4630 192nd Street East, Frederickson; *Site 4* (23 Acres)—Fife Business Park, Pacific Highway East, Fife; *Site 5* (170 acres)—Lakewood Industrial Park, 4700 100th Street Southwest, Lakewood; *Site 6* (76 acres)—Sumner Corporate Park, 1800 140th Avenue East, Sumner; *Site 7* (423 acres)—Cascadia Development Corp. Industrial Park, State Road 410, South Prairie; *Site 10* (123 acres)—Greenwater Corporate Park, East Valley Highway, Sumner; *Site 11* (185 acres)—Boeing Frederickson parcel, 18001 Canyon Road East, Frederickson; *Site 12* (160 acres)—J.R. & F. Randles parcel, 19209 Canyon Road East, Frederickson; *Site 13* (33 acres)—Rainier Corporate Park East, 70th Avenue East, Fife; and, *Site 14* (89 acres)—Trans-Pacific Industrial Park, 20th Street East, Fife.

For further information, contact Christopher Kemp at Christopher.Kemp@trade.gov or (202) 482-0862.

Dated: September 30, 2010.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2010-26064 Filed 10-14-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648-XW10

Vessel Monitoring Systems; Approved Mobile Transmitting Units and Communications Service Providers for Use in the Fisheries of the Western and Central Pacific

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

ACTION: Notice of vessel monitoring systems; type-approval.

SUMMARY: This document provides notice of vessel monitoring systems (VMS) approved by NOAA for use by vessels participating in the Western and Central Pacific Fishery, and sets forth relevant features of the VMS.

ADDRESSES: To obtain copies of the list of NOAA-approved VMS mobile transmitting units and NOAA-approved VMS communications service providers, please contact the VMS Support Center at (phone) 888-219-9228, (fax) 301-427-0049, or write to NOAA Fisheries

Office for Law Enforcement (OLE), VMS Support Center, 8484 Georgia Avenue, Suite 415, Silver Spring, MD 20910. For more addresses regarding approved VMS, see the **SUPPLEMENTARY INFORMATION** section under the heading "VMS Provider Addresses."

FOR FURTHER INFORMATION CONTACT: For questions regarding the status of VMS provider evaluations, contact Kelly Spalding, VMS Management Analyst, 301-427-2300; (fax) 301-427-0049. For questions regarding the Western and Central Pacific Fishery VMS requirement, contact Terry Boone, Pacific Islands Division VMS Program Manager, pidvms@noaa.gov, 808-203-2503.

SUPPLEMENTARY INFORMATION:**VMS Mobile Transceiver Units***Faria WatchDog 750VMS With VTERM*

The Faria WatchDog 750VMS with VTERM transceiver consists of an integrated dual model GPS/GSM/GPRS/Iridium Satellite Communicator or a single mode GPS/Iridium Satellite Communicator mounted in the wheelhouse and antennas mounted atop the vessel. The Faria VTERM is a 7-inch color touch screen display and provides the capability (if so configured) to process electronic forms, declarations, and to send e-mail. The unit is pre-configured and tested for NOAA Fisheries Service VMS Operations.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is a car-radio-sized transceiver powered by a 9.5 to 36 VDC power supply. The unit can be configured for automatic reduced position transmissions when the vessel is stationary (i.e., in port) which allows for port stays in a reduced power state and without the need for unit shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The Faria WatchDog 750VMS has omni-directional Iridium, GPS, and GSM/GPRS antennas, providing operation from ± 5 degrees above or below the horizon anywhere on Earth. The GSM/GPRS capability (if activated) gives the system the additional ability to communicate through the AT&T GPRS wireless network where available.

A configuration option is available to automatically send daily status reports to a private e-mail address and position reports to a secure Web site where the data is provided on a map and in tabular form. A 2-inch LCD user interface is also included with this system that displays if the MTU is operating properly and can send emergency notification

messages to up to four e-mail addresses and/or telephone numbers. A complete list of options is available from the VMS provider.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading "VMS Provider Addresses." The owner should identify himself or herself as a vessel owner issued a permit to operate in the Western and Central Pacific Fishery so the transceiver set can be properly configured.

The Thrane & Thrane Sailor (TT-3026D) Gold VMS

The TT-3026D Gold VMS features an integrated GPS/Inmarsat-C unit. The unit is factory pre-configured for NMFS VMS operations (non-Global Maritime Distress & Safety System (non-GMDSS)). The TT-3026D Gold VMS includes a marine-grade monitor with keyboard and integrated mouse. Satellite commissioning services are provided by GMPCS personnel.

Automatic GPS position reporting starts after transceiver installation and power activation onboard the vessel. The unit is an integrated transceiver/antenna/GPS design using a floating 10 to 32 VDC power supply. The unit is configured for automatic reduced position transmissions when the vessel is stationary (*i.e.*, in port). It allows for port stays without power drain or power shut down. The unit restarts normal position transmission automatically when the vessel goes to sea.

The TT-3026D provides operation down to ± 15 degree angles. The unit has the capability (if so configured) of two-way communications to send electronic forms and to receive e-mail and other messages. A configuration option is available to automatically send position reports to a private address, such as a fleet management company.

To use the TT-3026D, the vessel owner will need to establish an Inmarsat-C system use contract with an approved Inmarsat-C communications service provider. The owner will be required to complete the Inmarsat-C Registration for Service Activation for Maritime Mobile Earth Station. The owner should consult with GMPCS when completing this form.

GMPCS personnel will perform the following services before shipment: (1) Configure the transceiver according to OLE specifications for vessels issued permits to operate in the Western and Central Pacific Fishery; (2) download the predetermined NMFS position reporting and broadcast command identification numbers into the unit; (3) test the unit to ensure operation when installation has been completed on the

vessel; and (4) forward the Inmarsat service provider and the transceiver identifying information to OLE.

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading "VMS Provider Addresses." The owner should identify himself or herself as a vessel owner issued a permit to operate in the Western and Central Pacific Fishery so the transceiver set can be properly configured.

CLS America Thorium VMS TST-100

The approved configuration consists of the CLS America Thorium VMS TST-100 Transceiver and the Data Terminal Equipment (DTE) version 1.0. The DTE software is version 1.0. The CLS Thorium VMS unit and the DTE must be bundled with Halios communications (e-mail, eforms) and position services. This configuration is enabled through the Iridium Short Burst Data (SBD) service, and is accessed through the CLS Iridium Web Portal (IWP) or machine-to-machine interface (IWS).

A vessel owner may purchase this system by contacting the entity identified in this notice under the heading "VMS Provider Addresses." The owner should identify himself or herself as a vessel owner issued a permit to operate in the Western and Central Pacific Fishery so the transceiver set can be properly configured.

Communications Service Providers

OLE has approved the below-listed communications service providers for the Western and Central Pacific Fishery: GSM/Iridium for Faria Watchdog 750VMS with VTERM; Stratos Global and Vizada satellite communications services for the Thrane and Thrane Sailor (TT-3026D) Gold VMS; and Halios/Iridium for the CLS America Thorium TST-100 VMS.

The owner must confirm the operation and communications service to ensure that position reports are automatically sent to and received by OLE before leaving on a fishing trip under VMS. OLE does not regard the fishing vessel as being in compliance until position reports are automatically received. For confirmation purposes, contact the VMS support center at 888-219-9228 or ole.helpdesk@noaa.gov.

Faria GSM/Iridium Service

The Faria Watchdog GSM/Iridium Service is a dual mode GSM/GPRS and Iridium platform to ensure that connections are highly reliable, near real time and cost effective. The primary channel is the GSM/GPRS (if activated) and the secondary channel is Iridium.

INMARSAT-C Communications Providers

It is recommended, for vendor warranty and customer service purposes, that the vessel owner keep for his or her records (and that Stratos Global or Vizada have on record) the following identifying information: (a) Signed and dated receipts and contracts; (b) transceiver serial number; (c) Vizada or Stratos Global customer number, user name and password; (d) e-mail address of transceiver; (e) Inmarsat identification number; (f) owner name; (g) vessel name; (h) vessel documentation or registration number; and (i) mobile earth station license (FCC license).

CLS America Halios/Iridium Service

Thorium VMS TST-100 VMS must be bundled with Halios communications (e-mail, eforms) and position services, enabled through the (SBD) service, and accessed through the CLS (IWP) or (IWS).

VMS Provider Addresses

For Faria Watchdog/Iridium information, contact Faria WatchDog Inc., P.O. Box 486, Uncasville, CT 06382, mark@fariawatchdog.net; (860) 608-5875; (fax): (860) 848-9005.

For Thrane & Thrane Sailor 3026D Gold VMS, Stratos Global or Vizada information contact GMPCS Personal Communications Inc., 1501 Green Rd., Suite A-B, Pompano Beach, FL 33064; vms@GMPCS-US.com; (954) 973-3100; (fax): (954) 973-4800.

For CLS America Thorium VMS TST-100 and Halios/Iridium information, contact CLS America, Inc., 1441 McCormick Drive, Suite 1050, Largo, MD 20774; userservices@clsamerica.com; (301) 925-4411; (fax): (301) 925-8995.

Dated: October 12, 2010.

Samuel D. Rauch III,

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

[FR Doc. 2010-26071 Filed 10-14-10; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions And Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a product and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities and to delete products previously furnished by such agencies.

DATES: Comments Must Be Received On or Before: November 15, 2010.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202-3259.

FOR FURTHER INFORMATION CONTACT: Patricia Briscoe, Telephone: (703) 603-7740, Fax: (703) 603-0655, or e-mail CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the product and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the product and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following product and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Product

NSN: 8345-00-NSH-0015—Yellow Vinyl Panel Marker

NPA: Development Workshop, Inc., Idaho Falls, ID

Contracting Activity: BUREAU OF LAND MANAGEMENT, FA-NATIONAL INTERAGENCY FIRE CENTER, BOISE, ID

Coverage: C-List for 100% of the requirement of the FA-National Interagency Fire Center as aggregated by the Bureau of Land Management, FA-National Interagency Fire Center.

Services

Service Type/Location: Property Management Service, National Park Service Horace M. Albright Training Center, 1 Albright Avenue Grand Canyon, AZ

NPA: Trace, Inc., Boise, ID

Contracting Activity: DEPT OF THE INTERIOR, NATIONAL PARK SERVICE, DENVER SERVICE CENTER (DSC), DENVER, CO

Service Type/Location: Custodial Service, FEMA Louisiana Recovery Office, 1500 Main Street, Baton Rouge, LA

NPA: Goodworks, Inc., Metairie, LA

Contracting Activity: DEPT OF HOMELAND SECURITY, FEDERAL EMERGENCY MANAGEMENT AGENCY, BATON ROUGE, LA

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the products proposed for deletion from the Procurement List.

End of Certification

The following products are proposed for deletion from the Procurement List:

Products:

Hanger, Magnetic (Picture)

NSN: 5340-00-916-4209-6x6"

NSN: 5340-00-916-4208-6x7"

NSN: 5340-00-916-4207-3x6"

NPA: Knox County Association for Retarded Citizens, Knoxville, TN

Contracting Activity: GSA/FAS SOUTHWEST SUPPLY CENTER (QSDAC), FORT WORTH, TX

Blanket, Bed

NSN: 7210-00-177-4986

NPA: Chautauqua County Chapter, NYSARC, Jamestown, NY

Contracting Activity: GSA/FAS SOUTHWEST SUPPLY CENTER (QSDAC), FORT WORTH, TX

Toner, Cartridges, New

NSN: 7510-00-417-1222

NPA: Alabama Industries for the Blind, Talladega, AL

Contracting Activity: GSA/FSS OFC SUP CTR—PAPER PRODUCTS, NEW YORK, NY

Patricia Briscoe,

Deputy Director, Business Operations.

[FR Doc. 2010-26046 Filed 10-14-10; 8:45 am]

BILLING CODE 6353-01-P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement for the Louisiana Coastal Area—Plaquemines Parish, LA, Medium Diversion With Dedicated Dredging at Myrtle Grove Feasibility Study

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent.

SUMMARY: The U.S. Army Corps of Engineers (USACE) intends to prepare a Draft Environmental Impact Statement (EIS) for the Louisiana Coastal Area (LCA)—Louisiana, Medium Diversion at Myrtle Grove with Dedicated Dredging project. The proposed restoration feature consists of a diversion, coupled with dedicated dredging, that would allow the reintroduction of freshwater, sediment and nutrients into the critically effected area of the Barataria Basin, which is located in the Ascension, Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Charles, St. James, and St. John the Baptist parishes, Louisiana. This particular combination of restoration features would allow for rapid creation of wetland acreage and enable long-term stability. This EIS will be tiered off of the programmatic EIS for the LCA Ecosystem Restoration Study, November 2004. The record of decision for the programmatic EIS was signed on November 18, 2005.

DATES: See SUPPLEMENTARY INFORMATION section for scoping meeting dates.

For Further Information Contact: Questions concerning the draft EIS

should be addressed to Patricia S. Leroux, CEMVN-PDR-RS, P.O. Box 60267, New Orleans, LA 70160-0267; telephone: (504) 862-1544; fax: (504) 862-2088; or by e-mail: patricia.s.leroux@usace.army.mil.

SUPPLEMENTARY INFORMATION:

1. *Authority.* This EIS will be tiered off of the programmatic EIS for the LCA Ecosystem Restoration Study, November 2004. The record of decision for the programmatic EIS was signed on November 18, 2005. The Water Resources Development Act of 2007 (WRDA 2007) authorized the LCA program. The authority includes requirements for comprehensive planning, program governance, implementation, and other program components. The LCA restoration program facilitates the implementation of critical restoration features and essential science and technology demonstration projects, increasing the beneficial use of dredged material and determining the need for modifications of selected existing projects to support coastal restoration objectives. The LCA near-term plan includes fifteen elements authorized for implementation contingent upon meeting certain reporting requirements. Specifically, Section 7006(c)(1) authorizes the Secretary of the Army to carry out the five specifically named near-term projects substantially in accordance with the restoration plan set out in the Chief's Report dated January 31, 2005. The five elements are: (1) Mississippi River Gulf Outlet Environmental Restoration, (2) Small Diversion at Hope Canal, (3) Barataria Basin Barrier Shoreline Restoration, (4) Small Bayou Lafourche Reintroduction, and (5) Medium Diversion at Myrtle Grove with Dedicated Dredging. The Congressional authorization further states that before the Secretary may begin construction of any project under this subsection, the Secretary shall submit a report documenting any modification to the project, including cost changes, to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Environment and Public Works of the Senate.

2. *Proposed Action.* As recommended in the 2005 Chief's Report, the restoration feature consists of a freshwater diversion ranging from 2,500 to 15,000 cubic feet per second (cfs) coupled with dedicated dredging for the creation of up to 19,700 acres of new wetlands. The project would allow the reintroduction of freshwater, sediment and nutrients into the critically effected area of the Barataria Basin in a manner

similar to the rise and fall of the river's hydrological cycle. This combination would allow for rapid creation of wetland acreage and long-term stability. It is also expected to maximize the amount of acreage created per yard of sediment placed by capitalizing on incremental accretion of diverted sediment.

3. *Public Involvement.* Public involvement, an essential part of the EIS process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the EIS process would be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially and politically acceptable EIS. Public involvement would include but is not limited to: information dissemination; identification of problems, needs and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution by consensus; public and scoping notices and meetings; public, stakeholder and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

4. *Scoping.* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the EIS, would be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives that would be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues. A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings will be mailed to all interested parties in October 2011.

5. *Coordination.* The USACE and the U.S. Fish and Wildlife Service (USFWS) have formally committed to work together to conserve, protect, and restore fish and wildlife resources while ensuring environmental sustainability of our Nation's water resources under the January 22, 2003, Partnership Agreement for Water Resources and Fish and Wildlife. The USFWS will provide a Fish and Wildlife Coordination Act Report. Coordination

will be maintained with the USFWS and the National Marine Fisheries Service (NMFS) regarding threatened and endangered species under their respective jurisdictional responsibilities. Coordination will be maintained with the NMFS regarding essential fish habitat. Coordination will be maintained with the Natural Resources Conservation Service regarding prime and unique farmlands. The U.S. Department of Agriculture will be consulted regarding the "Swampbuster" provisions of the Food Security Act. Coordination will be maintained with the U.S. Environmental Protection Agency concerning compliance with Executive Order 12898, "Federal Action to Address Environmental Justice in Minority Populations and Low-Income Populations." Coordination will be maintained with the Advisory Counsel on Historic Preservation and the State Historic Preservation Officer. The Louisiana Department of Natural Resources will be consulted regarding consistency with the Coastal Zone Management Act. The Louisiana Department of Wildlife and Fisheries will be consulted concerning potential impacts to Natural and Scenic Streams.

6. *Availability of Draft EIS.* The earliest that the draft EIS would be available for public review would be in October of 2012. The draft EIS or a notice of availability will be distributed to affected Federal, state, and local agencies, Indian tribes, and other interested parties.

Edward R. Fleming,

Colonel, U.S. Army, District Commander.

[FR Doc. 2010-25987 Filed 10-14-10; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Availability of Final Environmental Impact Statement for the Sunridge Properties in the Sunridge Specific Plan Area, in Rancho Cordova, Sacramento County, CA, ID SPK-2009-00511

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers, Sacramento District, (Corps) is issuing a Final Environmental Impact Statement (EIS) which analyzes programmatically the direct, indirect and cumulative effects associated with six residential development projects in

the Sunridge Specific Plan area in Rancho Cordova, Sacramento County, CA.

The purpose of the EIS is to provide decision-makers and the public with information pertaining to the Proposed Action and alternatives, and disclose environmental impacts and identify mitigation measures to reduce impacts. The Proposed Action is the construction of the six projects (collectively, the "Sunridge Properties") which would require the filling of approximately 29.7 acres of waters of the United States, including wetlands. The EIS has been prepared as part of ongoing litigation concerning Department of the Army (DA) permits issued by the Corps between 2005 and 2007 for five of the projects and a pending DA permit decision for the sixth. A stay in the litigation is in place for the Corps to complete the EIS.

The EIS was prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the Corps' regulations for NEPA implementation at 33 Code of Federal Regulations parts 230 and 325 Appendix B. The Corps is the lead Federal agency responsible for complying with NEPA and information contained in the EIS serves as the basis for decisions regarding issuance of a DA permit.

DATES: Comments on the Final EIS must be submitted to the Corps by November 15, 2010.

ADDRESSES: Please send written comments to Michael Jewell, Chief of the Regulatory Division, U.S. Army Corps of Engineers, Sacramento District, 1325 J Street, Room 1480, Sacramento, CA 95814-2922. You may also e-mail your comments to

michael.s.jewell@usace.army.mil.

FOR FURTHER INFORMATION CONTACT: Michael Jewell, (916) 557-6605, e-mail: *michael.s.jewell@usace.army.mil*.

SUPPLEMENTARY INFORMATION: The Sunridge Specific Plan area is a master-planned area consisting of nine residential and commercial developments located in eastern Rancho Cordova, Sacramento County, CA. The Specific Plan, which was originally approved by the County of Sacramento in 2002, is part of a larger planning effort in the City of Rancho Cordova called the Sunrise-Douglas Community Plan. Three of the nine projects in the Sunridge Specific Plan area have been built. The Proposed Action is the construction of the remaining six projects in the Specific Plan area. Collectively, these six projects are referred to as the Sunridge Properties. The overall purpose of the action is to

construct a large residential development, including supporting infrastructure, in southeastern Sacramento County, California.

Between 2005 and 2007, the Corps completed Environmental Assessments, made Findings of No Significant Impact, and issued DA permits for five of the six Sunridge Specific Plan projects. The permitted projects are Anatolia IV, Sunridge Village J, Grantline 208, Douglas Road 98, and Douglas Road 103. A DA permit decision has not been rendered for the sixth project, Arista Del Sol.

The EIS includes an evaluation of a reasonable range of alternatives, including several on-site and off-site alternatives. Three alternatives were carried through for detailed analysis: (1) The no action alternative, (2) the proposed action (the applicants' preferred projects), and (3) a reduced footprint alternative. The no action alternative is limited to development in uplands, avoiding all waters of the United States. The reduced development footprint alternative involves less development with fewer impacts to waters of the United States.

A Draft EIS was issued on July 2, 2010. The Draft EIS was noticed in the **Federal Register** on July 2, 2010 (Vol. 75, No. 127, page 38502) and a public notice was issued by the Corps, both soliciting public input. The Corps also held public meetings on July 27, 2010, regarding the EIS. During the public review period, the Corps received eleven letters with comments. The Final EIS includes responses to each of the comments received.

Comments on the Final EIS must be submitted to the Corps by November 15, 2010. The public and affected federal, state, and local agencies, Native American tribes, and other organizations and parties are invited to comment. Electronic copies of the Draft EIS may be found on the Corps' Web site at <http://www.spk.usace.army.mil/organizations/cespk-co/regulatory/EISs/EIS-index.html>. A hard copy of the Final EIS may also be requested by contacting Michael Jewell. In addition to this notice, the Corps will issue a public notice advising interested parties of the availability of the Final EIS. Interested parties may register for Corps' public notices at:

<http://www.spk.usace.army.mil/organizations/cespk-co/regulatory/pnlist.html>. All comments on the Final EIS will be addressed in the Record of Decision.

Dated: October 5, 2010.

Michael S. Jewell,

Chief, Regulatory Division, Sacramento District, U.S. Army Corps of Engineers.

[FR Doc. 2010-25989 Filed 10-14-10; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Chief of Engineers Environmental Advisory Board

AGENCY: Department of the Army, U.S. Army Corps of Engineers DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following committee meeting:

Name of Committee: Chief of Engineers Environmental Advisory Board (EAB).

Topic: The EAB will discuss national considerations related to ecosystem restoration through integrated water resources management with emphasis on long-term recovery in the Gulf of Mexico, sea level rise in south Florida, and progress and status of South Florida ecosystem restoration.

Date of Meeting: October 29, 2010.

Place: The Westin Colonnade, 180 Aragon Avenue, Coral Gables, Florida 33134.

Time: 9 a.m. to 12 p.m.

Thirty minutes will be set aside for public comment. Members of the public who wish to speak are asked to register prior to the start of the meeting. Registration will begin at 8:30 a.m. Statements are limited to 3 minutes.

FOR FURTHER INFORMATION CONTACT: Ms. Rennie Sherman, Executive Secretary, *rennie.h.sherman@usace.army.mil*, 202-761-7771.

SUPPLEMENTARY INFORMATION: The EAB advises the Chief of Engineers by providing expert and independent advice on environmental issues facing the Corps of Engineers. The public meeting will include discussion between the EAB and the Chief of Engineers and may include presentations related to the topics of discussion. The meeting is open to the public, and public comment is tentatively scheduled for 30 minutes beginning at 11:15.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2010-25988 Filed 10-14-10; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF ENERGY**DOE/NSF High Energy Physics Advisory Panel**

AGENCY: Department of Energy, Office of Science.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF High Energy Physics Advisory Panel (HEPAP). Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, October 26, 2010; 9 a.m.–6 p.m.

ADDRESSES: Hilton Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: John Kogut, Executive Secretary; High Energy Physics Advisory Panel; U.S. Department of Energy; SC-25/ Germantown Building, 1000 Independence Avenue, SW., Washington, DC 20585-1290; Telephone: 301-903-1298.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of high energy physics research.

Tentative Agenda: Agenda will include discussions of the following:

Tuesday, October 26, 2010

- Discussion of proposal to run the Fermilab Tevatron Collider for three additional years (2012–2014) beyond the completion of its currently planned program.

- Public Comment (10-minute rule).
Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact John Kogut, 301-903-1298 or John.Kogut@science.doe.gov. You must make your request for an oral statement at least 5 business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Panel will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. This notice is being published less than 15 days before the date of the meeting due to programmatic issues.

Minutes: The minutes of the meeting will be available on the U.S. Department

of Energy's Office of High Energy Physics Advisory Panel Web site at <http://www.science.doe.gov/hep/panels/index.shtml>.

Issued in Washington, DC on October 8, 2010.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2010-26004 Filed 10-14-10; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. P-12642-003]

Wilkesboro Hydroelectric Company; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

October 7, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* P-12642-003.

c. *Date filed:* September 29, 2009.

d. *Applicant:* Wilkesboro Hydroelectric Company.

e. *Name of Project:* W. Kerr Scott Hydropower Project.

f. *Location:* The proposed project would be located at the existing U.S. Army Corps of Engineers' (Corps) W. Kerr Scott dam on the Yadkin River, near Wilkesboro in Wilkes County, North Carolina. A total of 3.5 acres of Federal lands, administered by the Corps, would be occupied by the proposed project.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Mr. Kevin Edwards, P.O. Box 143, Mayodan, NC 27027; Mr. Dean Edwards, P.O. Box 1565, Dover, FL 33527.

i. *FERC Contact:* Jennifer Adams at (202) 502-8087, or jennifer.adams@ferc.gov.

j. The deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice and reply comments are due 105 days from the issuance date of this notice.

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 <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 seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project.

Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

l. The proposed project would use the Corps' existing Kerr Scott dam, and would consist of the following modified and new facilities: (1) A multi-level intake structure with trashracks; (2) a 749-foot-long reinforced concrete water conduit with a 580-foot-long, 11-foot-diameter steel liner in the downstream portion; (3) a penstock bifurcation and two 8-foot-diameter steel penstocks; (4) a gate at the end of the water conduit, with a Howell-Bunger-ring-jet-type fixed cone valve; (5) an 80-foot-long by 30-foot-wide powerhouse containing one 2.0-MW Kaplan unit and one 2.0-MW propeller-type unit; (6) an 80-foot-wide by 30-foot-long discharge channel that joins the Yadkin River at the downstream end of the existing stilling basin; (7) a substation; (8) a new underground 12.47-kilovolt (kV) transmission line that extends 150 feet from the proposed powerhouse to an existing utility pole to the south of the powerhouse, and an upgraded 3,600-foot-long, 12.47-kV three-phase line that connects the utility pole to a Duke Energy substation; and (9) appurtenant facilities. The proposed Kerr Scott Project, using releases from the reservoir, as directed by the Corps, would generate approximately 22,400 megawatt-hours of energy annually.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be

viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary link." Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

All filings must: (1) Bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (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 submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions, or prescriptions must set forth their evidentiary basis, and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via e-mail of new filings and issuances related to this, or other pending projects. For assistance, contact FERC Online Support.

n. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to, and in compliance with, public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

o. A license applicant must file, no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25960 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11-3-000]

ANR Pipeline Company; Notice of Application

October 7, 2010.

Take notice that on October 6, 2010, ANR Pipeline Company (ANR), 717 Texas Street, Suite 2400, Houston, Texas 77002-2761, filed in Docket No. CP11-3-000 an application pursuant to section 7 of the Natural Gas Act (NGA), as amended, for permission and approval to abandon by sale certain natural gas facilities located between Eugene Island Blocks 307 and 305, offshore Louisiana, to Dynamic Offshore Resources NS, LLC (Dynamic), a natural gas producer, all as more fully set forth in the application which is on file with the Commission and open to the public for inspection. This filing may be also 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, please contact FERCO Online Support at FERCOOnlineSupport@ferc.gov or toll free at (866) 208-3676, or TTY, contact (202) 502-8659.

ANR proposes to abandon by sale approximately its Line 607 (4.41 miles of 16-inch diameter pipeline)¹ and appurtenances, located in Eugene Island Blocks 307, 306, and 305 to Dynamic, pursuant to their June 10, 2010, Pipeline Repair and Purchase and Sale Agreement. ANR states that it would cost an estimated \$25,186,000 to replicate the Line 607 facilities today and that no construction or removal of facilities would be required in this proposal. ANR further states that upon abandonment of the Line 607 facilities, Dynamic intends to operate the facilities as non-jurisdictional facilities and ANR further requests that the Commission consider the Line 607 Facilities to be non-jurisdictional gathering not subject to jurisdiction under Section 1 (b) of the Natural Gas Act.

Any questions concerning this application may be directed to Rene Staeb, Manager, Project Determinations & Regulatory Administration, ANR Pipeline Company, 717 Texas Street, Houston, Texas 77002, or via telephone at (832) 320-5215, facsimile (832) 320-

6215, or e-mail rene_staeb@transcanada.com.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

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 commenters 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 the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters 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.

¹ ANR constructed the Line 607 facilities, which connect to ANR's Line 606, under authorization granted in Docket No. CP77-386-000 [59 FPC 2164 (1977)].

The Commission strongly encourages electronic filings of comments, protests and interventions via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (<http://www.ferc.gov>) under the "e-Filing" link.

Comment Date: October 28, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25954 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11-67-001]

ONEOK Gas Storage, L.L.C.; Notice of Baseline Filing

October 7, 2010.

Take notice that on October 1, 2010, ONEOK Gas Storage, L.L.C. submitted a revised baseline filing of its Statement of Operating Conditions for services provided under Section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for

review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern time on Wednesday, October 20, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25964 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11-57-001]

Lobo Pipeline Company L.P.; Notice of Baseline Filing

October 7, 2010.

Take notice that on October 1, 2010, Lobo Pipeline Company L.P. submitted a revised baseline filing of its Statement of Operating Conditions for services provided under Section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission,

888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern time on Wednesday, October 20, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25963 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice Of Filings #1

October 6, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1951-001.

Applicants: NextEra Energy Services Massachusetts, L.

Description: NextEra Energy Services Massachusetts, LLC submits tariff filing per 35: NextEra Energy Services Mass, LLC Compliance Filing to be effective 12/31/9998.

Filed Date: 10/06/2010.

Accession Number: 20101006-5051.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-26-000.

Applicants: Ashtabula Wind III, LLC.

Description: Ashtabula Wind III, LLC submits tariff filing per 35.12: Ashtabula Wind III, LLC Market-Based Rate Application to be effective 10/5/2010.

Filed Date: 10/05/2010.

Accession Number: 20101005-5099.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Docket Numbers: ER11-27-000.

Applicants: LSP Safe Harbor Holdings, LLC.

Description: LSP Safe Harbor Holdings, LLC submits tariff filing per 35.12: Application for Market-Based Rates to be effective 11/15/2010.

Filed Date: 10/05/2010.

Accession Number: 20101005-5105.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Docket Numbers: ER11–28–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): Att GG FINAL 2 to be effective 12/5/2010.

Filed Date: 10/05/2010.
Accession Number: 20101005–5135.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Docket Numbers: ER11–30–000.
Applicants: Wisconsin Public Service Corporation.

Description: Wisconsin Public Service Corporation Depreciation Study & Change in Depreciation Rates.

Filed Date: 10/05/2010.
Accession Number: 20101005–5150.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Docket Numbers: ER11–31–000.
Applicants: Grand Ridge Energy LLC.
Description: Grand Ridge Energy LLC submits tariff filing per 35.12: Baseline Filing of Assignment, Co-Tenancy and Shared Facilities Agreement to be effective 10/6/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5042.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–32–000.
Applicants: Grand Ridge Energy II LLC.

Description: Grand Ridge Energy II LLC submits tariff filing per 35.12: Baseline Filing of Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/6/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5043.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–33–000.
Applicants: Grand Ridge Energy III LLC.

Description: Grand Ridge Energy III LLC submits tariff filing per 35.12: Baseline Filing of Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/6/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5044.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–34–000.
Applicants: Grand Ridge Energy IV LLC.

Description: Grand Ridge Energy IV LLC submits tariff filing per 35.12: Baseline Filing of Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/6/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5045.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–35–000.
Applicants: Grand Ridge Energy V LLC.

Description: Grand Ridge Energy V LLC submits tariff filing per 35.12: Baseline Filing of Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/6/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5047.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–36–000.
Applicants: KD Power Marketing Services, LLC.

Description: Notice of Cancellation of Market-Based Rate Tariff for KD Power Marketing Services, LLC.

Filed Date: 10/06/2010.
Accession Number: 20101006–5048.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–37–000.
Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits an executed Wholesale Market Participating Agreement with PPL Renewable Energy and Metropolitan Edison Co, to be effective 9/17/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5049.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–38–000.
Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): WMPA No. 2647, V2–046, among PJM, Pilesgrove Solar Power and Atlantic City to be effective 9/17/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5050.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on

or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–26041 Filed 10–14–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

October 7, 2010.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–2–000.
Applicants: Noble Wethersfield Windpark, LLC, Noble Chateaugay Windpark, LLC, Noble Belmont Windpark, LLC, Noble Ellenburg Windpark, LLC, Noble Bliss Windpark, LLC, Noble Clinton Windpark I, LLC, Noble Great Plains Windpark, LLC, MSD Capital, L.P., Noble Altona Windpark, LLC.

Description: Application for Authorization of Transaction Pursuant to Section 203 of the Federal Power Act of Noble Altona Windpark, LLC, *et al.*

Filed Date: 10/06/2010.
Accession Number: 20101006–5124.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: EC11–3–000.
Applicants: Harbor Gen Holdings, LLC, LSP Safe Harbor Holdings, LLC, PPL University Park, LLC, PPL Wallingford Energy LLC, PPL Holtwood, LLC.

Description: Harbor Gen Holdings, LLC, LSP Safe Harbor Holdings, LLC, PPL, Joint Application For Approval Under Section 203 of the Federal Power Act and Request for Expedited Treatment.

Filed Date: 10/06/2010.
Accession Number: 20101006–5125.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11–3–000.
Applicants: Flat Water Wind Farm, LLC.

Description: Self-Certification of EG of Flat Water Wind Farm, LLC.

Filed Date: 10/06/2010.
Accession Number: 20101006–5055.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: EG11–4–000.
Applicants: Wildorado Wind Two, LLC.

Description: Notice of Self-Certification of Wildorado Wind Two, LLC as an Exempt Wholesale Generator.

Filed Date: 10/07/2010.
Accession Number: 20101007–5085.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER01–1099–014; ER02–1406–015; ER99–2928–011.
Applicants: Cleco Power LLC; Acadia Power Partners, LLC; Cleco Evangeline LLC.

Description: Cleco Power LLC submits narrative responses to the Commission's eight request, supported by the files, exhibits *etc.* re the notice of non-material change in status 3/25/10.

Filed Date: 10/01/2010.
Accession Number: 20101004–0042.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER07–1247–002.
Applicants: FC Energy Services Company, LLC.

Description: Waiver request of FC Energy Services Company, LLC.

Filed Date: 10/07/2010.
Accession Number: 20101007–5067.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–1951–001.
Applicants: NextEra Energy Services Massachusetts, LLC.

Description: NextEra Energy Services Massachusetts, LLC submits tariff filing per 35: NextEra Energy Services Mass, LLC Compliance Filing to be effective 12/31/9998.

Filed Date: 10/06/2010.
Accession Number: 20101006–5051.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER10–2068–003.
Applicants: Delaware City Refining Company LLC.

Description: Delaware City Refining Company LLC submits tariff filing per 35: Revised Market-Based Rates Tariff to be effective 10/1/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5062.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2073–001.
Applicants: Northern States Power Company.

Description: Northern States Power Company submits Compliance Filing of the Certificates of Concurrences and Related Tariff Records *etc.*, to be effective 7/30/2010.

Filed Date: 09/28/2010.
Accession Number: 20100928–5452.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.

Docket Numbers: ER10–2077–002.
Applicants: PBF Power Marketing LLC.

Description: PBF Power Marketing LLC submits tariff filing per 35: Revised Market-Based Rates Tariff to be effective 10/1/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5063.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2438–002.
Applicants: ISO New England Inc.

Description: ISO New England Inc. submits baseline tariff filing to restore tariff language previously accepted by the Commission, to be effective 8/30/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5021.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2556–000.
Applicants: NRG Southaven LLC.
Description: NRG Southaven, LLC submits a notice of Cancellation of their market-based rate tariff, FERC Electric Tariff, original Volume 1.

Filed Date: 09/08/2010.
Accession Number: 20100908–0201.
Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER10–2614–001.

Applicants: ENMAX Energy Marketing Inc.
Description: Updated Market Power Analysis of ENMAX Energy Marketing Inc.

Filed Date: 10/06/2010.
Accession Number: 20101006–5079.
Comment Date: 5 p.m. Eastern Time on Monday, December 06, 2010.

Docket Numbers: ER10–2750–001.
Applicants: The Order of St. Benedict of New Hampshire.

Description: The Order of St. Benedict of New Hampshire submits Substitute Original Sheet 1 to Rate Schedule FERC No 1.

Filed Date: 10/06/2010.
Accession Number: 20101007–0200.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER10–2783–001.
Applicants: Arthur Kill Power LLC.
Description: Arthur Kill Power LLC submits tariff filing per 35: Arthur Kill—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5008.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2784–001.
Applicants: Astoria Gas Turbine Power LLC.

Description: Astoria Gas Turbine Power LLC submits tariff filing per 35: Astoria Gas Turbine—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5009.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2795–001.
Applicants: Conemaugh Power LLC.
Description: Conemaugh Power LLC submits tariff filing per 35: Conemaugh Power—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5010.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2798–001.
Applicants: Connecticut Jet Power LLC.

Description: Connecticut Jet Power LLC submits tariff filing per 35: Connecticut Jet—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5011.
Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2799–001.
Applicants: Devon Power LLC.
Description: Devon Power LLC submits tariff filing per 35: Devon

Power—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5012.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2801–001.

Applicants: Dunkirk Power LLC.

Description: Dunkirk Power LLC submits tariff filing per 35: Dunkirk—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5013.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2846–001.

Applicants: Huntley Power LLC.

Description: Huntley Power LLC submits tariff filing per 35: Huntley—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5014.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2875–001.

Applicants: Keystone Power LLC.

Description: Keystone Power LLC submits tariff filing per 35: Keystone—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5017.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2878–001.

Applicants: Middleton Power LLC.

Description: Middleton Power LLC submits tariff filing per 35: Middleton—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5064.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2879–001.

Applicants: Montville Power LLC.

Description: Montville Power LLC submits tariff filing per 35: Montville—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5065.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2880–001.

Applicants: NEO Freehold LLC.

Description: NEO Freehold LLC submits tariff filing per 35: NEO Freehold—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5066.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2888–001.

Applicants: Norwalk Power LLC.

Description: Norwalk Power LLC

submits tariff filing per 35: Norwalk—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5068.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2896–001.

Applicants: NRG Energy Center Dover LLC.

Description: NRG Energy Center Dover LLC submits tariff filing per 35: NRG Energy Center Dover—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5070.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2913–001.

Applicants: NRG Energy Center Paxton LLC.

Description: NRG Energy Center Paxton LLC submits tariff filing per 35: NRG Energy Center Paxton—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5074.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2914–001.

Applicants: NRG New Jersey Energy Sales LLC.

Description: NRG New Jersey Energy Sales LLC submits tariff filing per 35: NRG New Jersey Energy Sales—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5075.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2915–001.

Applicants: NRG Rockford II LLC.

Description: NRG Rockford II LLC submits tariff filing per 35: NRG Rockford II—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5078.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2916–001.

Applicants: NRG Power Marketing LLC.

Description: NRG Power Marketing LLC submits tariff filing per 35: NRG Rockford—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5076.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2932–001.

Applicants: Somerset Power LLC.

Description: Somerset Power LLC

submits tariff filing per 35: Somerset—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5080.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2947–001.

Applicants: Vienna Power LLC.

Description: Vienna Power LLC submits tariff filing per 35: Vienna Power—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5081.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–2969–001.

Applicants: Oswego Harbor Power LLC.

Description: Oswego Harbor Power LLC submits tariff filing per 35: Oswego Harbor—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5079.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER10–3223–001.

Applicants: Indian River Power LLC.

Description: Indian River Power LLC submits tariff filing per 35: Indian River—Amendment to Market-Based Rate Tariff to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007–5015.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11–39–000.

Applicants: Flat Water Wind Farm LLC.

Description: Flat Water Wind Farm LLC submits tariff filing per 35.12: Flat Water Wind Farm, LLC Market-Based Rate Application to be effective 10/7/2010.

Filed Date: 10/06/2010.

Accession Number: 20101006–5054.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11–40–000;

ER11–40–001.

Applicants: Arizona Public Service Company.

Description: Arizona Public Service Company submits tariff filing per 35.12: Rate Schedule No. 217, OMR Agreements between APS and Western, Part 1 of 2 to be effective 10/6/2010 and Part 2 of 2 to be effective 10/6/2010.

Filed Date: 10/06/2010.

Accession Number: 20101006–5065; 20101006–5066.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-41-000.

Applicants: AEP Retail Energy Partners.

Description: AEP Retail Energy Partners submits tariff filing per 35.12: 20101006 MBR AEP Retail EP Baseline to be effective 10/6/2010.

Filed Date: 10/06/2010.

Accession Number: 20101006-5077.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-42-000.

Applicants: Idaho Power Company.

Description: Idaho Power Company submits tariff filing per 35.13(a)(2)(iii): Revised Service Agreement for IMNAHA Oregon to be effective 10/1/2010.

Filed Date: 10/06/2010.

Accession Number: 20101006-5095.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-43-000.

Applicants: Black Hills Power, Inc.

Description: Black Hills Power, Inc. submits tariff filing per 35.13(a)(2)(iii): Revised BEPC NITSA to be effective 10/6/2010.

Filed Date: 10/06/2010.

Accession Number: 20101006-5113.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-44-000.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(i): PGE TRBA RSBA ECRBA 2011 Rate Filing to be effective 1/1/2011.

Filed Date: 10/06/2010.

Accession Number: 20101006-5115.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-45-000.

Applicants: Deutsche Bank AG.

Description: Deutsche Bank AG submits Notice of Cancellation in the form required by the Commission's regulations for the purpose of terminating its market-based electric tariff.

Filed Date: 10/06/2010.

Accession Number: 20101007-0201.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 27, 2010.

Docket Numbers: ER11-46-000.

Applicants: AEP Energy Partners, Inc.

Description: AEP Energy Partners, Inc. submits tariff filing per 35.12: 20101007 AEP EP MBR Baseline to be effective 8/1/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5019.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-47-000.

Applicants: Indiana Michigan Power Company, Appalachian Power Company, Ohio Power Company, Kingsport Power Company, Columbus Southern Power Company, Kentucky Power Company, Wheeling Power Company.

Description: Indiana Michigan Power Company submits its baseline market-based rate tariff, FERC Electric Tariff, First Revised Volume No 5, to be effective 10/8/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5020.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-48-000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35: Compliance Filing to Incorporate ER09-1051-004 Approved Revisions into eTariff to be effective 8/30/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5061.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-50-000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35: Compliance Filing to Incorporate ER10-2232-000 Approved Revisions into eTariff to be effective 8/30/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5082.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-51-000.

Applicants: Mississippi Power Company.

Description: Mississippi Power Company submits tariff filing per 35: MRA Tariff Initial Filing to be effective 10/7/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5083.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-52-000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35: Compliance Filing to Incorporate ER07-397-005 Approved Revisions into eTariff to be effective 8/30/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5097.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Docket Numbers: ER11-53-000.

Applicants: FC Energy Services Company, LLC.

Description: FC Energy Services Company, LLC submits tariff filing per 35.12: FC Energy MBR Baseline to be effective 10/7/2010.

Filed Date: 10/07/2010.

Accession Number: 20101007-5127.

Comment Date: 5 p.m. Eastern Time on Thursday, October 28, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's

eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010-26042 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

October 5, 2010.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11-1-000.

Applicants: Broad River Energy LLC, Broad River OL-1, LLC, Broad River OL-2, LLC, Broad River OL-3, LLC, Broad River OL-4, LLC, South Point Energy Center, LLC, South Point OL-1, LLC, South Point OL-2, LLC, South Point OL-3, LLC, South Point OL-4, LLC, Calpine BRSP, LLC.

Description: Calpine BRSP, LLC, *et al.* Joint Application For Approval Under Section 203 of the FPA.

Filed Date: 10/04/2010.

Accession Number: 20101004-5212.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11-1-000.

Applicants: Ashtabula Wind III, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Ashtabula Wind III, LLC.

Filed Date: 10/01/2010.

Accession Number: 20101001-5165.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: EG11-2-000.

Applicants: Iberdrola Renewables, Inc.

Description: Self-Certification of EG of Iberdrola Renewables, Inc. for Blue Creek Wind LLC.

Filed Date: 10/01/2010.

Accession Number: 20101001-5173.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER02-2263-012.

Applicants: Southern California Edison Company.

Description: Change in status report of Southern California Edison Company.

Filed Date: 09/30/2010.

Accession Number: 20100930-5508.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER06-613-010.

Applicants: ISO New England Inc., New England Power Pool

Description: Ninth Compliance Report of ISO New England Inc. Regarding Forward Reserve Markets.

Filed Date: 10/01/2010.

Accession Number: 20101001-5215.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER07-1112-013;

ER01-2765-029; ER02-2102-029;

ER00-2885-030; ER03-1283-023;

ER05-1232-026; ER07-1113-013;

ER07-1116-012; ER07-1117-015;

ER07-1356-015; ER07-1358-016;

ER09-1141-009; ER09-609-006; ER07-

1118-014.

Applicants: J.P. Morgan Ventures Energy Corporation, BE Allegheny LLC, BE CA LLC, BE Ironwood LLC, BE KJ LLC, BE Rayle LLC, BE Alabama LLC, BE Louisiana LLC, Cedar Brakes I, L.L.C., Utility Contract Funding, L.L.C., Vineland Energy LLC, Central Power & Lime LLC, Cedar Brakes II, L.L.C., J.P. Morgan Commodities Canada Corporation

Description: JPMorgan Sellers' Supplement to Notice of Non-Material Change in Status.

Filed Date: 10/01/2010.

Accession Number: 20101001-5321.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER07-1208-003;

ER07-1222-002; ER07-1223-002;

ER09-297-003; ER10-1017-001; ER10-

1020-001; ER10-1078-001; ER10-1048-

002; ER10-1079-001; ER10-1080-001;

ER10-1081-001; ER10-1143-001;

ER10-1145-001; ER10-75-001; ER10-

87-001; ER07-1246-004; ER07-1202-

004;

Applicants: Exelon New Boston LLC, Exelon Generating Company, LLC, Commonwealth Edison Company, PECO Energy Company, Wind Capital Holdings, LLC, CR Clearing, LLC, Cow Branch Wind Power LLC, JD WIND 4, LLC, Harvest WindFarm, LLC, Exelon West Medway LLC, Exelon Wyman LLC, Exelon Framingham LLC, Exelon New England Power Marketing, LP, Exelon Energy Company, Cassia Gulch Wind Park, Michigan Wind 1, LLC, Tuana Springs Energy, LLC.

Description: Notification of Change in Status Commonwealth Edison Company, et. al.

Filed Date: 10/01/2010.

Accession Number: 20101001-5328.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-622-002;

ER99-845-020.

Applicants: Puget Sound Energy, Inc., Macquarie Energy LLC.

Description: Revisions to Triennial Updated Market Analysis by Puget Sound Energy, Inc. and Macquarie Energy LLC.

Filed Date: 10/04/2010.

Accession Number: 20101004-5214.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER10-1509-001.

Applicants: Louisville Gas and Electric Company.

Description: Louisville Gas and Electric Company submits tariff filing per 35: OATT Compliance Filing 10_04_10 to be effective 7/18/2010.

Filed Date: 10/04/2010.

Accession Number: 20101004-5197.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER10-1510-001.

Applicants: Kentucky Utilities Company.

Description: Kentucky Utilities Company submits tariff filing per 35: 10_04_10 KU OATT Concurrence Compliance Filing to be effective 7/18/2010.

Filed Date: 10/04/2010.

Accession Number: 20101004-5198.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER10-1563-001.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35: 2010-10-04 CAISO's Baseline Electronic Tariff Compliance Filing to be effective 6/28/2010.

Filed Date: 10/04/2010.

Accession Number: 20101004-5195.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER10-2291-001.

Applicants: Westmoreland Partners.

Description: Westmoreland Partners submits tariff filing per 35: Baseline Market-Based Rate (Re-File) to be effective 9/20/2010.

Filed Date: 09/17/2010.

Accession Number: 20100917-5156.

Comment Date: 5 p.m. Eastern Time on Friday, October 8, 2010.

Docket Numbers: ER10-2778-001.

Applicants: Rainbow Energy Marketing Corp.

Description: Rainbow Energy Marketing Corp. submits tariff filing per 35: Rainbow Energy Marketing Amendment to Market-Based Rate Tariff to be effective 12/6/2010.

Filed Date: 10/05/2010.

Accession Number: 20101005-5060.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Docket Numbers: ER10-2789-001.

Applicants: Rainbow Energy Ventures, LLC.

Description: Rainbow Energy Ventures, LLC submits tariff filing per 35: Rainbow Energy Ventures Amendment to Market-Based Rate Tariff to be effective 12/3/2010.

Filed Date: 10/04/2010.

Accession Number: 20101004-5199.

Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER10-3324-000.

Applicants: Indeck-Yerkes Limited Partnership.

Description: Indeck-Yerkes Limited Partnership submits tariff filing per 35.12: Indeck-Yerkes Limited Partnership, FERC Electric MBR Tariff No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5001.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3325-000.

Applicants: SESCO CALISO.

Description: SESCO CALISO submits its baseline tariff filing to FERC Electric Tariff Schedule No. 1, First Revised Volume No 1, to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5002.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3326-000.

Applicants: SESCO Enterprises LLC.

Description: SESCO Enterprises LLC submits tariff filing per 35.12: SESCO Enterprises, LLC FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5003.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3327-000.

Applicants: Jump Power LLC.

Description: Jump Power LLC submits tariff filing per 35.12: Jump Power, LLC, FERC Electric MBR Tariff No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5004.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3328-000.

Applicants: SESCO Enterprises Canada Ltd.

Description: SESCO Enterprises Canada Ltd. submits tariff filing per 35.12: SESCO Enterprises Canada, Ltd., FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5005.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3329-000.

Applicants: Round Rock Energy LP.

Description: Round Rock Energy LP submits tariff filing per 35.12: Round Rock Energy, LP FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5006.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3330-000.

Applicants: Round Rock Energy LLC.

Description: Round Rock Energy LLC submits tariff filing per 35.12: Round Rock Energy, LLC FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5007.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3331-000.

Applicants: West Oaks Energy NY/NE, LP.

Description: West Oaks Energy NY/NE, LP submits tariff filing per 35.12: West Oaks Energy NY/NE, LP, FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5008.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3332-000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company submits tariff filing per 35.12: Concurrence-Transmission Capacity Use & Exchange Agreement to be effective 11/19/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5012.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER10-3333-000.

Applicants: Commonwealth Edison Company, Commonwealth Edison Co. of Indiana, Inc.

Description: Report of ComEd, ComEd submits Cancellation of Interconnection Agreement with Power Partners Midwest.

Filed Date: 09/30/2010.

Accession Number: 20100930-5506.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER10-3334-000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company request for cancellation of FERC Electric Tariff Volume No. 2 as part of the FERC Order 714 baseline filing.

Filed Date: 09/30/2010.

Accession Number: 20100930-5507.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER10-3335-000.

Applicants: International Transmission Company.

Description: International Transmission Company submits a Notice of Cancellation of its Open Access Transmission Tariff to confirm the cancellation of the OATT effective 9/30/10.

Filed Date: 09/30/2010.

Accession Number: 20101001-0201.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER10-3336-000.

Applicants: Michigan Electric Transmission Co., LLC.

Description: Michigan Electric Transmission Company, LLC submits a Notice of Cancellation of its Open Access Transmission Tariff to confirm the cancellation of the OATT effective 9/30/10.

Filed Date: 09/30/2010.

Accession Number: 20101001-0202.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER10-3337-000.

Applicants: Ridgewind Power Partners, LLC.

Description: Application of Ridgewind Power Partners, LLC for Order Accepting Initial Market-Based Rate Tariff, Granting Certain Waivers and Blanket Approvals and Request for Expedited Consideration.

Filed Date: 09/30/2010.

Accession Number: 20101001-0203.

Comment Date: 5 p.m. Eastern Time on Thursday, October 21, 2010.

Docket Numbers: ER11-1-000.

Applicants: Duke Energy Carolinas, LLC.

Description: Duke Energy Carolinas, LLC submits tariff filing per 35: Order No. 739 Compliance Filing to be effective 9/24/2010.

Filed Date: 10/01/2010.

Accession Number: 20101001-5081.

Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-2-000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii) Schedule 24 Tariff Revisions to Comply with Order Nos. 676-E and 676-F to be effective 12/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5082.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-3-000.
Applicants: California Independent System Operator Corporation.
Description: California Independent System Operator Corporation submits tariff filing per 35: 2010-10-01 CAISO's Notice of Termination of MSA with Corona to be effective 9/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5090.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-4-000.
Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35: Compliance (ER10-2186) to be effective 10/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5121.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-5-000.
Applicants: Great Bay Energy, LLC.
Description: Great Bay Energy, LLC submits tariff filing per 35.12: Great Bay Energy, LLC, FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5129.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-6-000.
Applicants: Great Bay Energy I LLC.
Description: Great Bay Energy I LLC submits tariff filing per 35.12: Great Bay Energy I, LLC, FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5131.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-7-000.
Applicants: Velocity American Energy Master I, LP.

Description: Velocity American Energy Master I, LP submits tariff filing per 35.12: Velocity American Energy Master I, LP FERC Electric Tariff Schedule No. 1 to be effective 9/30/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5132.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-8-000.
Applicants: Southern Company Services, Inc.

Description: Southern Company Services, Inc.'s Annual Informational

Filing Updating FERC Annual Charge and Attachment K Regional Transmission-Planning Cost Components under its OATT.

Filed Date: 10/01/2010.
Accession Number: 20101001-5232.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-9-000.
Applicants: El Paso Electric Company.
Description: Order No. 618 Filing of El Paso Electric Company to Reflect Updated Depreciation Rates in the Formula Rate of Rio Grande Electric Cooperative.

Filed Date: 10/01/2010.
Accession Number: 20101001-5236.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-10-000.
Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii) 2021R1 and 2022R1 Kansas City Power and Light Company PTP to be effective 9/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5239.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-11-000.
Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii) 1641R4 Grand River Dam Authority NITSA and NOA to be effective 9/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5244.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-12-000.
Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii) PJM submits Marginal Loss Calculation Definitions to be effective 6/1/2012.

Filed Date: 10/01/2010.
Accession Number: 20101001-5289.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-13-000.
Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35: Order No. 676-E/F and 729 Compliance Filing to be effective 7/26/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5290.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-14-000.

Applicants: Sierra Pacific Power Company.

Description: Sierra Pacific Power Company submits tariff filing per 35.12: Transmission Interconnection Agreement-Robinson Summit to be effective 12/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5303.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-15-000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits revisions to Attachment O transmission rate formula under the Open Access Transmission, Energy & Operating Reserve Markets Tariff, effective 12/1/10.

Filed Date: 10/04/2010.
Accession Number: 20101004-5000.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11-16-000.
Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii) 10-1-10 BREC Pricing Zone to be effective 12/1/2010.

Filed Date: 10/04/2010.
Accession Number: 20101004-5001.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11-17-000.
Applicants: Nevada Power Company.

Description: Nevada Power Company submits tariff filing per 35.12: Transmission Interconnection Agreement-Harry Allen to be effective 12/1/2010.

Filed Date: 10/01/2010.
Accession Number: 20101001-5304.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11-18-000.
Applicants: Central Hudson Gas & Electric Corporation.

Description: Central Hudson Gas & Electric Corporation submits tariff filing per 35: CHG&E Rate Schedules & Service Agreements—Order 714, to be effective 10/5/2010.

Filed Date: 10/04/2010.
Accession Number: 20101004-5047.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11-19-000.
Applicants: WSPP Inc.

Description: WSPP Inc. submits tariff filing per 35.13(a)(2)(iii) Revisions to List of Members in the WSPP Agreement Filing to be effective 8/17/2010.

Filed Date: 10/04/2010.

Accession Number: 20101004–5058.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11–20–000.
Applicants: LP & T Energy LLC.
Description: LP and T Energy LLC submit notice of cancellation of Original Sheet No 1 *et al* to its FERC Electric Tariff, Original Volume No 1, effective 11/1/10 under ER11–20.

Filed Date: 10/01/2010.
Accession Number: 20101004–0201.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11–21–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35: Compliance Filing (ER10–1955) to be effective 10/4/2010.

Filed Date: 10/04/2010.
Accession Number: 20101004–5145.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11–22–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii) H075 GIA to be effective 10/5/2010.

Filed Date: 10/04/2010.
Accession Number: 20101004–5193.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11–23–000.
Applicants: Participating Transmission Owners Administrator.
Description: Filing Parties submits a request waiver of certain business practice standards in Version 002.1 of the Wholesale Electric Quadrant Adopted by the North American Energy Standards Board.

Filed Date: 10/04/2010.
Accession Number: 20101005–0200.
Comment Date: 5 p.m. Eastern Time on Monday, October 25, 2010.

Docket Numbers: ER11–24–000.
Applicants: New England Power Pool.
Description: The New England Power Pool Participants Committee submits transmittal letter along with the counterpart signature pages of the agreement dated 9/1/71 etc.

Filed Date: 10/01/2010.
Accession Number: 20101005–0201.
Comment Date: 5 p.m. Eastern Time on Friday, October 22, 2010.

Docket Numbers: ER11–25–000.
Applicants: Avista Corporation.
Description: Avista Corporation submits tariff filing per 35.13(a)(2)(iii) Avista Corp OATT Service Agreement No. T–1084 to be effective 10/5/2010 under ER11–00025–000 Filing Type: 10

Filed Date: 10/05/2010.
Accession Number: 20101005–5068.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 26, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's

eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–26040 Filed 10–14–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 1

October 8, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–37–000.
Applicants: PPL EnergyPlus, LLC, PPL Generation, LLC, Harbour Gen Holdings, LLC.

Description: Request of PPL Generation, LLC, PPL EnergyPlus, LLC, and Harbor Gen Holdings, LLC for Temporary Waiver, Expedited Consideration, and Shortened Notice Period.

Filed Date: 10/05/2010.
Accession Number: 20101005–5151.
Comment Date: 5 p.m. Eastern Time on Friday, October 15, 2010.

Docket Numbers: RP11–38–000.
Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Sequent 10–6–10 to be effective 10/1/2010.

Filed Date: 10/06/2010
Accession Number: 20101006–5078.
Comment Date: 5 p.m. Eastern Time on Monday, October 18, 2010.

Docket Numbers: RP11–39–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.

Description: Kinder Morgan Interstate Gas Transmission LLC submits tariff filing per 154.204: Negotiated Rate 2010–09–30 Aventure NC to be effective 10/15/2010.

Filed Date: 10/06/2010.
Accession Number: 20101006–5080.
Comment Date: 5 p.m. Eastern Time on Monday, October 18, 2010.

Docket Numbers: RP11–40–000.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company files a Petition for a Limited Waiver of Northern's FERC Gas Tariff in order to allow Northern to resolve prior period imbalance trading errors with Northern States Power Company.
Filed Date: 10/06/2010.
Accession Number: 20101006–5122.
Comment Date: 5 p.m. Eastern Time on Monday, October 18, 2010.
Docket Numbers: RP11–41–000.
Applicants: Texas Eastern Transmission, LP.
Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: Negotiated Rate—PSEG ERT to be effective 11/1/2010.
Filed Date: 10/07/2010.
Accession Number: 20101007–5007.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–42–000.
Applicants: Steuben Gas Storage Company.
Description: Steuben Gas Storage Company submits tariff filing per 154.602: Central New York Oil and Gas FERC Gas Tariff 1st Revise Volume 1 Tariff Cancellation to be effective 10/7/2010.
Filed Date: 10/07/2010.
Accession Number: 20101007–5077.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–43–000.
Applicants: Central New York Oil And Gas, LLC.
Description: Central New York Oil And Gas, LLC submits tariff filing per 154.203: Central New York Oil and Gas FERC Gas Tariff 1st Revise Volume 1 to be effective 10/7/2010.
Filed Date: 10/07/2010.
Accession Number: 20101007–5105.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–44–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Kinder Morgan Interstate Gas Transmission LLC submits tariff filing per 154.204: Negotiated Rate 10–07–10 Mico to be effective 10/8/2010.
Filed Date: 10/07/2010.
Accession Number: 20101007–5126.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–45–000.
Applicants: Columbia Gulf Transmission Company.
Description: Columbia Gulf Transmission Company submits tariff filing per 154.204: Evergreen Non-Conforming 10.8.10 to be effective 11/7/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5129.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–46–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Columbia Gas Transmission, LLC submits tariff filing per 154.204: Evergreen Non-Conforming 10.7.10 to be effective 11/7/2010.
Filed Date: 10/07/2010.
Accession Number: 20101007–5134.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.
Docket Numbers: RP11–47–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: East Tennessee Natural Gas, LLC submits tariff filing per 154.204: Form of Service Agreements Modification to be effective 11/8/2010.
Filed Date: 10/08/2010.
Accession Number: 20101008–5029.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 20, 2010.
Docket Numbers: RP11–48–000.
Applicants: Egan Hub Storage, LLC.
Description: Egan Hub Storage, LLC submits tariff filing per 154.204: Form of Service Agreements Modification to be effective 11/8/2010.
Filed Date: 10/08/2010.
Accession Number: 20101008–5030.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 20, 2010.
Docket Numbers: RP11–49–000.
Applicants: Saltville Gas Storage Company L.L.C.
Description: Saltville Gas Storage Company L.L.C. submits tariff filing per 154.204: Form of Service Agreements Modification to be effective 11/8/2010.
Filed Date: 10/08/2010.
Accession Number: 20101008–5032.
Comment Date: 5 p.m. Eastern Time on Wednesday, October 20, 2010.
 Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need

not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,
 Deputy Secretary.

[FR Doc. 2010–26043 Filed 10–14–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 2

October 8, 2010.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP10–1304–002.
Applicants: Gulf States Transmission Corporation.

Description: Gulf States Transmission Corporation submits tariff filing per 154.203: Gulf States Transmission Corp. Correction to Order No. 587–U Compliance Filing to be effective 11/1/2010.

Filed Date: 10/07/2010.
Accession Number: 20101007–5000.
Comment Date: 5 p.m. Eastern Time on Tuesday, October 19, 2010.

Docket Numbers: RP10–1343–001.
Applicants: Energy West Development, Inc.

Description: Energy West Development, Inc. resubmits their baseline filing, FERC Gas Tariff, First Revised Volume No 1 in compliance with the Commission's 3/19/10 Order, to be effective 10/27/2010.

Filed Date: 10/08/2010.

Accession Number: 20101008-5000.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 20, 2010.

Docket Numbers: RP10-1400-001.

Applicants: Chandeaur Pipe Line Company.

Description: Chandeaur Pipe Line Company submits revised tariff Sections 2, 8.2, et al to its FERC Gas Tariff, Third Revised Volume No 1 pursuant to Order 587-U, to be effective 11/1/2010.

Filed Date: 10/08/2010.

Accession Number: 20101008-5001.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 20, 2010.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2010-26044 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM11-2-000]

Smart Grid Interoperability Standards; Notice of Docket Designation for Smart Grid Interoperability Standards

October 7, 2010.

1. The Energy Independence and Security Act of 2007 (EISA)¹ lays out the policy of the United States with regard to modernization of the nation's electricity transmission and distribution system and directs the development of a framework to achieve interoperability of smart grid devices and systems, including protocols and model standards for information management.² EISA directs the National Institute of Standards and Technology (NIST) to coordinate the development of this framework. Once the Commission is satisfied that NIST's work has led to "sufficient consensus" on interoperability standards, EISA directs the Commission to "institute a rulemaking proceeding to adopt such standards and protocols as may be necessary to insure smart-grid functionality and interoperability in interstate transmission of electric power, and regional and wholesale electricity markets."³

2. In August 2009, NIST launched a three-phase plan to expedite the development of smart grid interoperability standards. In the first phase, NIST led the smart grid community in a participatory public process to identify applicable standards, as well as priorities for additional standardization activities. In January 2010, NIST released a framework and roadmap that identified a number of standards that are applicable to the ongoing development of the smart grid.⁴ After further discussion with stakeholders and an analysis of the standards' cyber security protections, NIST has now identified five suites of standards that it states are ready for consideration by regulatory authorities. While the Commission has made no determination yet on whether "sufficient consensus" exists for these standards, the Commission is issuing this notice to

¹ Public Law 110-140, 121 Stat. 1492 (2007).

² EISA 1305(a), to be codified at 15 U.S.C. 17385(a).

³ EISA 1305(d), to be codified at 15 U.S.C. 17385(d).

⁴ *Framework and Roadmap for Smart Grid Interoperability Standards, Release 1.0*, NIST Special Publication 1108, January 2010, available at http://www.nist.gov/public_affairs/releases/upload/smartgrid_interoperability_final.pdf.

designate the docket captioned above for a possible rulemaking proceeding pursuant to EISA section 1305(d).

3. In accordance with the Federal Administrative Procedure Act,⁵ the Commission will issue a Notice of Proposed Rulemaking for comment before adopting any of the five suites of standards identified by NIST.

4. For the convenience of interested stakeholders, the Commission has placed NIST's announcement and descriptions of the standards that have been prepared by NIST in the record of this proceeding. These documents are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site under the above docket number at <http://www.ferc.gov> using the eLibrary link. For assistance, please contact FERC, Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25965 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10-480-000]

Central New York Oil and Gas Company, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed MARC I Hub Line Project and Request for Comments on Environmental Issues, and Notice of Public Scoping Meeting and Onsite Review

September 22, 2010.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the MARC I Hub Line Project involving construction and operation of facilities by Central New York Oil and Gas Company, LLC (CNYOG) in Bradford, Sullivan, and Lycoming Counties, Pennsylvania. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project.

⁵ 5 U.S.C. 551-59; 701-06 (2006).

Your input will help the Commission staff determine what issues need to be evaluated in the EA. Please note that the scoping period will close on October 25, 2010.

Comments may be submitted in written form or verbally. Further details on how to submit written comments are provided in the Public Participation section of this notice. In lieu of or in addition to sending written comments, the Commission invites you to attend the public scoping meeting scheduled as follows: FERC Public Scoping Meeting, MARC I Hub Line Project, October 13, 2010, at 6:30 p.m., Sullivan County Court House, 245 Muncy Street, Laporte, PA.

On October 13 and 14, 2010, the Office of Energy Projects staff will be in the MARC I Hub Line Project area to gather data related to the environmental analysis. Staff will examine the proposed route and aboveground facility locations and possible modifications to the proposed facilities. This will assist staff in completing its comparative evaluation of environmental impacts of the proposed project. Viewing of this area is anticipated to be from public access points.

All interested parties planning to attend must provide their own transportation. Those attending should meet at the following location:

On both October 13 and 14, 2010, at 8:30 a.m.: Sullivan County Road House, Route 220, Muncy Valley, PA.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives are asked to notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" was attached to the project notice CNYOG provided to landowners. This fact sheet addresses a number of typically-asked questions, including the

use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (<http://www.ferc.gov>).

Summary of the Proposed Project

CNYOG proposes to construct and operate about 39 miles of 30-inch-diameter pipeline (the MARC I Hub Line), a total of 31,660 horsepower (hp) of compression, metering and regulating facilities, and appurtenant facilities in Bradford, Sullivan, and Lycoming Counties, Pennsylvania. The MARC I Hub Line Project would provide transportation service of about 550,000 dekatherms of natural gas per day, and would have a maximum allowable operating pressure of 1260 pounds per square inch gauge. According to CNYOG, its project would provide interstate pipeline infrastructure to receive natural gas produced from Marcellus Shale production areas for delivery to existing interstate pipeline systems of Tennessee Gas Pipeline Company (TGP), CNYOG, and Transcontinental Gas Pipeline Corporation (Transco). It would also provide for bi-directional transportation between TGP, CNYOG, and Transco.

The MARC I Hub Line Project would consist of the following facilities:

- The MARC I Hub Line consisting of approximately 39 miles of 30-inch-diameter pipeline extending southward from interconnections with CNYOG's South Lateral and TGP's Line 300 in Bradford County, through Sullivan County, and ending at an interconnection with Transco's Leidy Line in Sullivan County, all in Pennsylvania;

- The M1-N Unit consisting of 15,300 hp of additional electric-driven compression, filter separators, gas coolers, and electrical infrastructure at CNYOG's NS2 Compressor Station on CNYOG's South Lateral proposed in Docket No CP10-194-000;

- The M1-S Compressor Station consisting of 16,360 hp of gas-driven compression, gas coolers, filter separators, and a 300 kilovolt (nominal) emergency generator located on the MARC I Hub Line about 3 miles north of the proposed interconnection with Transco's Leidy Line;

- The Northern Meter Station at the NS2 Compressor Station including metering facilities, valves, filter separator, and related telemetry equipment;

- The Southern Meter Station at the Transco interconnection including metering facilities, valves, filter separator, related telemetry equipment,

and possibly odorant equipment for deliveries to Transco;

- Interconnections to gathering lines;
- Wareyards for temporary equipment and materials storage located near mileposts (MPs) 4.3, 10.6, and 16.0 of the MARC I Hub Line; and

- About 33 temporary access roads to be used during construction of the project, and permanent access roads to the Southern Meter Station and the M1-S Compressor Station.

The general location of the project facilities is shown in Appendix 1.¹

Land Requirements for Construction

Construction of the proposed facilities would disturb about 591 acres of land for the aboveground facilities and the pipeline, including access roads. Additional areas would be used for temporary wareyards or contractor yards to store equipment and materials. Following construction, about 236 acres would be maintained for permanent operation of the project's facilities; the remaining acreage would be restored and allowed to revert to former uses. About 4 percent of the proposed pipeline route parallels existing pipeline, utility, or road rights-of-way.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us² to discover and address concerns the public may have about proposals. This process is referred to as "scoping". The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;

¹ The appendices referenced in this notice are not being printed in the *Federal Register*. Copies of appendices were sent to all those receiving this notice in the mail and are available at <http://www.ferc.gov> using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

² "We", "us", and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species; and
- public safety.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be presented in the EA. The EA will be placed in the public record and, depending on the comments received during the scoping process, may be published and distributed to the public. A comment period will be allotted if the EA is published for review. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure your comments are considered, please carefully follow the instructions in the Public Participation section beginning on page 6.

With this notice, we are asking agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. These agencies may choose to participate once they have evaluated the proposal relative to their responsibilities. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, no agencies have expressed their intention to participate as a cooperating agency in the preparation of the EA to satisfy their NEPA responsibilities related to this project.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.³ We will define the

³ The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Historic properties are defined in those regulations as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register for Historic Places.

project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the project is further developed. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by CNYOG. This preliminary list of issues may be changed based on your comments and our analysis:

- Impacts on present and future land use;
- impacts on vegetation and wildlife;
- impacts on federally listed threatened and endangered species;
- impacts on water resources;
- impacts on cultural resources;
- erosion and sediment control;
- impacts on traffic caused by construction equipment;
- impacts due to construction and operation;
- pipeline route alternatives or variations;
- alternative access roads; and
- safety during construction and operation.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that they will be received in Washington, DC, on or before October 25, 2010.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP10-480-000) with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502-8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the eComment

feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. With eFiling you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If the EA is published for distribution, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (Appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Intervenor play a more

formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the "e-filing" link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC Web site at <http://www.ferc.gov> using the "eLibrary" link. Click on the eLibrary link, click on "General Search" and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.*, CP10-480-000). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <http://www.ferc.gov/esubscribenow.htm>.

Finally, public meetings or site visits will be posted on the Commission's calendar located at <http://www.ferc.gov/EventCalendar/EventsList.aspx> along with other related information.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010-25966 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR10-137-000]

Hill-Lake Gas Storage, LLC; Notice of Filing

October 7, 2010.

Take notice that on September 30, 2010, Hill-Lake Gas Storage, LLC (Hill-Lake) filed a revised Statement of Operating Conditions (SOC) for its Storage Services, proposing substantive

revisions to its tariff for administrative efficiency as more fully detailed in the application.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FercOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern time on Wednesday, October 20, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010-25962 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-27-000]

LSP Safe Harbor Holdings, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

October 7, 2010.

This is a supplemental notice in the above-referenced proceeding of LSP Safe Harbor Holdings, 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 October 27, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The 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 review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed

docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25957 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-26-000]

Ashtabula Wind III, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

October 7, 2010.

This is a supplemental notice in the above-referenced proceeding of Ashtabula Wind III, 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 October 27, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The 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 review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25956 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11-39-000]

Flat Water Wind Farm, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

October 7, 2010.

This is a supplemental notice in the above-referenced proceeding of Flat Water Wind Farm, 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 October 27, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be

listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The 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 review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25958 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10-509-000]

Sawgrass Storage LLC; Notice of Petition

October 7, 2010.

Take notice that on September 27, 2010, Sawgrass Storage LLC (Sawgrass Storage), 3333 Warrenville Road, Suite 630, Lisle, Illinois 60532, filed in Docket No. CP10-509-000, a petition for Exemption of Temporary Acts and Operations and Request for Expedited Approval, pursuant to Rule 207(a)(5) of the Commission's Rules of Practice and Procedure, and section 7(c)(1)(B) of the Natural Gas Act (NGA), to perform specific temporary activities related to drill site preparation and drilling of a test well and water well located in Lincoln Parish, Louisiana. Specifically, Sawgrass Storage proposes to drill a test well to determine the feasibility of developing a depleted natural gas production reservoir in the Vaughn Sandstone of the Cotton Valley formation into a natural gas storage facility, and a water well to assist in the drilling of the test well, all as more fully set forth in the application which is on

file with the Commission and open to public inspection. 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 to access the document. For assistance, call (202) 502-8659 or TTY, (202) 208-3676.

Any questions regarding this application should be directed to Stephen Cittadine, Vice President, Sawgrass Storage LLC, 3333 Warrenville Road, Suite 630, Lisle, Illinois 60532, or by calling (630) 245-7801 (telephone) or (630) 245-7839 (fax), scittad@nicor.com or to Christopher A. Schindler, Eric S. Lashner, Hogan Lovells US LLP, Columbia Square, 555 13th Street, NW., Suite 600, Washington, DC 20004, or by calling (202) 637-5723 (telephone) or (202) 637-5910 (fax), christopher.schindler@hoganlovells.com.

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.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit

14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

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 commentors 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 the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors 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 in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call

(866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: October 28, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25953 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13798-000]

Lanai Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

October 7, 2010.

On June 10, 2010, Lanai, 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 Lanai Pumped Storage Project to be located on the Pacific Ocean in the vicinity of Lanai City, in Maui County, Hawaii. 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) An artificial, lined 57-acre reservoir created by the construction of embankments; (2) an approximately 11,650-foot-long conduit joined to the Pacific Ocean; (3) three reversible pump-turbines, totaling 300 megawatts (MW) of generating capacity, with up to 100 MW of additional pumping capacity; (4) an approximately 6-mile-long, single-circuit 230-kilovolt transmission line; and (5) appurtenant facilities. The estimated annual generation of the Lanai Pumped Storage project would be 919,800 megawatt-hours.

Applicant Contact: Matthew Shapiro, CEO, Gridflex Energy, LLC, 725 1210 W. Franklin St., Suite 2, Boise, ID 83702; phone: (208) 246-9925.

FERC Contact: Shana Murray (202) 502-8333.

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. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site <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. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

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-13798-000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25961 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98-1-000]

Records Governing Off-the-Record Communications; Public Notice

October 5, 2010.

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding.

Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC, Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

| Docket No. | File date | Presenter or requester |
|-------------------------|-----------|--------------------------------|
| Prohibited: | | |
| 1. ER08-386-000. | 9-8-10 | Peter C. Luchsinger. |
| Exempt: | | |
| 1. CP09-35-000. | 9-14-10 | Elizabeth Kendziora. |
| 2. CP10-477-000. | 9-22-10 | Hon. John Barrow. |
| 3. CP10-494-000. | 9-30-10 | Ashley and Stuart Moberley. |
| 4. CP10-494-000. | 10-4-10 | Lisa Reddick. |
| 5. CP10-494-000. | 9-30-10 | Jackie and Victoria True-love. |
| 6. Project No. 606-000. | 9-16-10 | Hon. Wally Herger. |

| Docket No. | File date | Presenter or requester |
|--------------------------|-----------|------------------------|
| 7. Project No. 2621-000. | 9-29-10 | Jim Seay. ¹ |

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2010-26039 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Revocation of Market-Based Rate Tariff

October 7, 2010.

| | |
|--|---|
| Electric Quarterly Reports. BM2 LLC | Docket No. ER02-2001-016 Docket No. ER06-885-000 |
| DJGW, LLC | Docket No. ER04-289-000 |

On September 22, 2010, the Commission issued an order announcing its intent to revoke the market-based rate authority of the above captioned public utilities, which had failed to file their required Electric Quarterly Reports.¹ The Commission provided the utilities fifteen days in which to file their overdue Electric Quarterly Reports or face revocation of their market-based rate tariffs.

In Order No. 2001, the Commission revised its public utility filing requirements and established a requirement for public utilities, including power marketers, to file Electric Quarterly Reports summarizing the contractual terms and conditions in their agreements for all jurisdictional services (including market-based power sales, cost-based power sales, and transmission service) and providing transaction information (including rates) for short-term and long-term power sales during the most recent calendar quarter.²

In the September 22 Order, the Commission directed BM2 LLC and DJGW, LLC to file the required Electric Quarterly Reports within 15 days of the

¹ E-mail exchange with FERC staff.

¹ *Electric Quarterly Reports*, 132 FERC ¶ 61,251 (2010) (September 22 Order).

² *Revised Public Utility Filing Requirements*, Order No. 2001, 67 FR 31,043, FERC Stats. & Regs. ¶ 31,127, reh'g denied, Order No. 2001-A, 100 FERC ¶ 61,074, *reconsideration and clarification denied*, Order No. 2001-B, 100 FERC ¶ 61,342, *order directing filings*, Order No. 2001-C, 101 FERC ¶ 61,314 (2002), *order directing filing*, Order No. 2001-D, 102 FERC ¶ 61,334 (2003).

date of issuance of the order or face revocation of their authority to sell power at market-based rates and termination of their electric market-based rate tariffs.³

The time period for compliance with the September 22 Order has elapsed. The two companies identified in the September 22 Order (BM2 LLC and DJGW, LLC) have failed to file their delinquent Electric Quarterly Reports.

The Commission hereby revokes the market-based rate authority and terminates the electric market-based rate tariffs of the above-captioned public utilities.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25955 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at Southwest Power Pool Regional State Committee Meeting and Southwest Power Pool Board of Directors Meeting

October 7, 2010.

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool, Inc. (SPP) Regional State Committee, and SPP Board of Directors, as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

SPP Regional Entity Trustee Meeting

October 25, 2010 (8:30 a.m.–2 p.m.)
Kansas City Marriott Downtown, 200 West 12th Street, Kansas City, MO 64105, 816-421-6800.

SPP Regional State Committee Meeting

October 25, 2010 (1 p.m.–5 p.m.)
Kansas City Marriott Downtown, 200 West 12th Street, Kansas City, MO 64105, 816-421-6800.

SPP Board of Directors and Annual Meeting of Members

October 26, 2010 (8 a.m.–3 p.m.)
Kansas City Marriott Downtown, 200 West 12th Street, Kansas City, MO 64105, 816-421-6800.

The discussions may address matters at issue in the following proceedings:

Docket No. ER06-451, *Southwest Power Pool, Inc.*

Docket No. ER08-1419, *Southwest Power Pool, Inc.*

Docket No. ER09-35, *Tallgrass Transmission LLC*

Docket No. ER09-36, *Prairie Wind Transmission LLC*

Docket No. ER09-659, *Southwest Power Pool, Inc.*

Docket No. ER09-1050, *Southwest Power Pool, Inc.*

Docket No. ER09-1254, *Southwest Power Pool, Inc.*

Docket No. OA08-61, *Southwest Power Pool, Inc.*

Docket No. OA08-104, *Southwest Power Pool, Inc.*

Docket No. ER10-45, *Southwest Power Pool, Inc.*

Docket No. ER10-696, *Southwest Power Pool, Inc.*

Docket No. ER10-941, *Southwest Power Pool, Inc.*

Docket No. ER10-1069, *Southwest Power Pool, Inc.*

Docket No. ER10-1254, *Southwest Power Pool, Inc.*

Docket No. ER10-1269, *Southwest Power Pool, Inc.*

Docket No. ER10-1697, *Southwest Power Pool, Inc.*

Docket No. ER10-1960, *Southwest Power Pool, Inc.*

Docket No. ER10-2145, *Southwest Power Pool, Inc.*

Docket No. ER10-2416, *Southwest Power Pool, Inc.*

Docket No. ER10-2451, *Southwest Power Pool, Inc.*

Docket No. ER10-2452, *Southwest Power Pool, Inc.*

Docket No. ER10-2483, *Southwest Power Pool, Inc.*

Docket No. ER10-2489, *Southwest Power Pool, Inc.*

Docket No. ER10-2608, *Southwest Power Pool, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249-5937 or patrick.clarey@ferc.gov.

Kimberly D. Bose,
Secretary.

[FR Doc. 2010-25959 Filed 10-14-10; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-8993-2]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-1399 or <http://www.epa.gov/compliance/nepa/>.

Weekly receipt of Environmental Impact Statements
Filed 10/4/2010 through 10/8/2010
Pursuant to 40 CFR 1506.9.

Notice

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA has met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has been including its comment letters on EISs on its Web site at: <http://www.epa.gov/compliance/nepa/eisdata.html>. Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20100400, Final EIS, NPS, WY, Jackson Hole Airport Use Agreement Extension Project, To Enable Continued Air Transportation Services, Grand Teton National Park, Teton County, WY, Wait Period Ends: 11/15/2010, Contact: Mary Gibson Scott 307-739-3300.

EIS No. 20100401, Draft EIS, BIA, CA, Manzanita Casino—Manzanita Band of Kumeyaay Indians Fee-To-Trust and Casino Facility/Hotel Project, Construction and Operation, City of Calexico, Imperial County, CA, Comment Period Ends: 12/22/2010, Contact: John Rydzik, 916-978-6051.

EIS No. 20100402, Final EIS, USFS, WV, Fernow Experimental Forest Project, To Continue Long-Term Research Studies Involving Removal of Trees, Prescribed Burning, Fertilization, and Use of Herbicides and other Management Activities to Control Invasive Plant Species, Tucker County, WV, Wait Period Ends: 11/15/2010, Contact: Mary Beth Adams, 304-478-2000 Ext 130.

EIS No. 20100403, Draft EIS, NPS, MD, Hampton National Historic Site, General Management Plan, Implementation, Baltimore County, MD, Comment Period Ends: 12/14/2010, Contact: Peter Iris-Williams, 215-597-6479.

EIS No. 20100404, Final EIS, USFS, CA, Tahoe National Forest Motorized Travel Management Project, Proposed Changes to the National Forest Transportation System, Implementation, Nevada, Placer, Plumas, Sierra, and Yuba Counties,

³ September 22 Order at Ordering Paragraph A.

CA, Wait Period Ends: 11/15/2010, Contact: David Arrasmith, 530-478-6220.

EIS No. 20100405, Draft EIS, USFS, MT, Beaver Creek Landscape Management Project, Vegetation Treatment, Implementation, Ashland Ranger District, Custer National Forest, Powder River County, MT, Comment Period Ends: 11/29/2010, Contact: Walt Allen, 406-784-2596.

EIS No. 20100406, Final Supplement, USACE, LA, Calcasieu River and Pass, Louisiana Dredged Material Management Plan for 20 Years While Updating and Redefining the Base Plan, Implementation, Calcasieu Ship Channel, Port of Lake Charles, Calcasieu and Cameron Parishes, LA, Wait Period Ends: 11/15/2010, Contact: Sandra Stiles, 504-862-1583.

EIS No. 20100407, Final EIS, BLM, NV, Amargosa Farm Road Solar Energy Project, Construction and Operation of Two Concentrated Solar Power Plant Facilities, Right-of-Way Application on Public Lands, Nye County, NV, Wait Period Ends: 11/15/2010, Contact: Greg Helseth, 702-515-5023.

EIS No. 20100408, Draft Supplement, MMS, AK, Chukchi Sea Planning Area, Oil and Gas Lease Sale 193, Analyzing the Environmental Impact of Natural Gas Development and Evaluate Incomplete, Missing, and Unavailable Information, Chukchi Sea, Alaska Outer Continental Shelf, AK, Comment Period Ends: 11/29/2010, Contact: Deborah Cranswick, 907-334-5267.

EIS No. 20100409, Final EIS, NRC, IA, GENERIC—License Renewal of Nuclear Plants Regarding Duane Arnold Energy Center, Supplement 42 to NUREG-1437, near the Town of Palo, Linn County, IA, Wait Period Ends: 11/15/2010, Contact: Charles Eccleston, 301-415-8537.

Amended Notices

EIS No. 20100326, Draft EIS, NPS, SD, South Unit—Badlands National Park, General Management Plan, Implementation, SD, Comment Period Ends: 10/18/2010, Contact: Eric J. Brunnemann, 605-433-5361. Revision of FR Notice Published 08/20/2010: Extending Comment Period from 10/18/2010 to 11/01/2010.

EIS No. 20100391, Final EIS, USACE, NC, Surf City and North Topsail Beach Project, To Evaluate Coastal Storm Damage Reduction, Topsail Island, Pender and Onslow Counties, NC, Wait Period Ends: 11/08/2010, Contact: Scott Nicholson, 202-761-7770. Revision to FR Notice Published 10/8/2010: Change Wait Period from

11/22/2010 to 11/08/2010 and Change Contact Name and Number to Scott Nicholson, (202)761-7770.

Dated: October 12, 2010.

Cliff Rader,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. 2010-26073 Filed 10-14-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0588; FRL-8850-8]

FIFRA Scientific Advisory Panel; Notice of Cancellation of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Agency is issuing this notice to cancel a November 2-5, 2010 meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) to consider and review the Chlorpyrifos Physiologically-Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Modeling linked to the Cumulative and Aggregate Risk Evaluation System (CARES). The meeting was announced in the **Federal Register** of September 15, 2010; it will be rescheduled for early 2011.

FOR FURTHER INFORMATION CONTACT:

Sharlene Matten, Designated Federal Official (DFO), Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (202) 564-0130; *fax number:* (202) 564-8382; *e-mail address:* matten.sharlene@epa.gov.

SUPPLEMENTARY INFORMATION: The November 2-5, 2010 meeting of the FIFRA SAP to consider and review the Chlorpyrifos Physiologically-Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Modeling linked to the Cumulative and Aggregate Risk Evaluation System (CARES) has been cancelled. The meeting was announced in the **Federal Register** of September 15, 2010 (75 FR 56101) (FRL-8843-6). It will be rescheduled for early 2011. For further information, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 7, 2010.

Frank Sanders,

Director, Office of Science Coordination and Policy.

[FR Doc. 2010-25910 Filed 10-14-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9214-1]

National and Governmental Advisory Committees to the U.S. Representative to the Commission for Environmental Cooperation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Committee Act, Public Law 92-463, EPA gives notice of a meeting of the National Advisory Committee (NAC) and Governmental Advisory Committee (GAC) to the U.S. Representative to the North American Commission for Environmental Cooperation (CEC). The National and Governmental Advisory Committees advise the EPA Administrator in her capacity as the U.S. Representative to the CEC Council. The Committees are authorized under Articles 17 and 18 of the North American Agreement on Environmental Cooperation (NAAEC), North American Free Trade Agreement Implementation Act, Public Law 103-182, and as directed by Executive Order 12915, entitled "Federal Implementation of the North American Agreement on Environmental Cooperation." The NAC is composed of 12 members representing academia, environmental non-governmental organizations, and private industry. The GAC consists of 12 members representing state, local, and Tribal governments. The Committees are responsible for providing advice to the U.S. Representative on a wide range of strategic, scientific, technological, regulatory, and economic issues related to implementation and further elaboration of the NAAEC.

The purpose of the meeting is to provide advice on the CEC's 2011 Draft Operational Plan, the CEC's 2010-2015 Strategic Plan, and learn about regional environmental issues. The meeting will also include a public comment session. A copy of the agenda will be posted at <http://www.epa.gov/ocem/nacgac-page.htm>.

DATES: The National and Governmental Advisory Committees will hold an open meeting on Wednesday, November 17, from 12 p.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Astor Crowne Plaza, 739 Canal Street, New Orleans, Louisiana 70130. Telephone: 508-926-0500. The meeting is open to the public, with limited seating on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Oscar Carrillo, Designated Federal Officer, carrillo.oscar@epa.gov, 202-564-0347, U.S. EPA, Office of Cooperative Environmental Management (1601-M), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: Requests to make oral comments or provide written comments to the Committees should be sent to Oscar Carrillo, Designated Federal Officer, at the contact information above.

Meeting Access: For information on access or services for individuals with disabilities, please contact Oscar Carrillo at 202-564-0347 or carrillo.oscar@epa.gov. To request accommodation of a disability, please contact Oscar Carrillo, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: October 6, 2010.

Oscar Carrillo,

Designated Federal Officer.

[FR Doc. 2010-26065 Filed 10-14-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9214-2]

Science Advisory Board Staff Office; Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee (CASAC) to conduct a quality review and approve two draft reports from the CASAC Ambient Air Monitoring and Methods Subcommittee (AAMMS) and a draft report from the CASAC Oxides of Nitrogen (NO_x) and Sulfur Oxides (SO_x) Secondary National Ambient Air Quality Standards (NAAQS) Review Panel.

DATES: The public teleconference will be held on November 8, 2010 from 10 a.m. to 2 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning the teleconference may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 564-2073; fax (202) 564-2098; or e-mail at stallworth.holly@epa.gov. General information concerning the CASAC can be found on the EPA Web site at <http://www.epa.gov/casac>.

SUPPLEMENTARY INFORMATION:

Background: The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and national ambient air quality standards under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The CASAC will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the National Ambient Air Quality Standards (NAAQS) for the six "criteria" air pollutants.

As noted in 75 FR 51807-51808, the CASAC Ambient Air Monitoring and Methods Subcommittee held a public teleconference on September 15, 2010 to review EPA's white paper, *Approach for the Development of a New Federal Reference Method (FRM) for Lead (Pb) in Total Suspended Particles (TSP)*, which outlines the approach for the development a new FRM for lead. CASAC will review the draft report of the AAMMS that provides advice on issues identified in the white paper. Information on the CASAC AAMMS white paper review can be found at the CASAC Web site at: <http://yosemite.epa.gov/sab/sabproduct.nsf/0/0109B095F273EBA38525764600654702?OpenDocument>.

As noted in 75 FR 54146-54147, the Ambient Air Methods and Monitoring Subcommittee (AAMMS) of the Clean Air Scientific Advisory Committee (CASAC) met on September 29-30, 2010 to provide advice to EPA on its near-road monitoring guidance materials and

an associated pilot monitoring study. Specifically, EPA asked for advice on concepts and information that should be included in its forthcoming near-road monitoring guidance document, advice on how future near-road monitoring requirements for pollutants such as Carbon Monoxide (CO) and Particulate Matter (PM), may be drafted in a way to mesh with the existing Nitrogen Dioxide (NO₂) requirements and foster a multi-pollutant monitoring infrastructure, and the objectives, approach, and execution of the near-road monitoring pilot study. In response to EPA's charge questions, AAMMS is drafting a report to be reviewed by the chartered CASAC on November 9, 2010. Information on the CASAC AAMMS review of EPA's near-road monitoring guidance and pilot study may be found at: <http://yosemite.epa.gov/sab/sabproduct.nsf/0/9E0F3E9D727323C18525778900596432?OpenDocument>.

As noted in 75 FR 54871-54872, the Clean Air Scientific Advisory Committee NO_x and SO_x Secondary National Ambient Air Quality Standards Review Panel met on October 6-7, 2010 to peer review EPA's *Policy Assessment for the Review of the Secondary National Ambient Air Quality Standards for NO_x and SO_x: Second External Review Draft (September 2010)*. CASAC will review the draft report of the NO_x and SO_x Secondary NAAQS Review Panel that provides advice on the policy assessment. Information on the CASAC NO_x and SO_x Secondary NAAQS Review Panel's activity can be found on the CASAC Web site at: <http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/0f3c13c821ee6181a85257473005ae1ec!OpenDocument>.

Technical Contacts: (a) Any technical questions concerning the white paper entitled "*Approach for the Development of a New Federal Reference Method (FRM) for Lead (Pb) in Total Suspended Particles (TSP)*" can be directed to Ms. Joann Rice, OAQPS, at rice.joann@epa.gov or (919) 541-3372. The paper is posted at <http://www.epa.gov/ttn/amtic/casacinf.html>.

(b) Any technical questions concerning EPA's Near-Road Guidance Document Outline or Near-road Monitoring Pilot Study Objectives & Approach should contact Mr. Nealson Watkins at 919-541-5522 or watkins.nealson@epa.gov. These review documents may be found posted at <http://www.epa.gov/ttn/amtic/casacinf.html>.

(c) Any technical questions regarding the "*Policy Assessment for the Review of the Secondary National Ambient Air Quality Standards for NO_x and SO_x*:"

Second External Review Draft (September 2010)” should be directed to Dr. Byran Hubbell, OAR, at 919-541-0621 or hubbell.bryan@epa.gov. This review document can be accessed at <http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html>.

Availability of Meeting Materials: A meeting agenda and other materials for the meeting will be placed on the CASAC Web site on the Web page reserved for the teleconferences, accessible through the calendar link on the blue navigation sidebar at <http://www.epa.gov/casac>.

Procedures for Providing Public Input: Public comment for consideration by EPA’s federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. They should send their comments directly to the Designated Federal Officer for the relevant advisory committee. *Oral Statements:* To be placed on the public speaker list for the teleconference, interested parties should notify Dr. Holly Stallworth, DFO, by e-mail no later than November 2, 2010.

Individuals making oral statements will be limited to three minutes per speaker. *Written Statements:* Written statements for the teleconference should be received in the SAB Staff Office by November 2, 2010 so that the information may be made available to the CASAC Panel for its consideration prior to this meeting. Written statements should be supplied to the DFO via e-mail (acceptable file format: Adobe Acrobat PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Stallworth at the phone number or e-mail address noted above, preferably at least ten days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: October 7, 2010.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2010-26066 Filed 10-14-10; 8:45 am]

BILLING CODE 6560-50-P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

SES Performance Review Board—Appointment of Members

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members to the Performance Review Board of the Equal Employment Opportunity Commission.

FOR FURTHER INFORMATION CONTACT: Lisa M. Williams, Chief Human Capital Officer, U.S. Equal Employment Opportunity Commission, 131 M Street, NE., Washington, DC 20507, (202) 663-4306.

SUPPLEMENTARY INFORMATION:

Publication of the Performance Review Board (PRB) membership is required by 5 U.S.C. 4314(c)(4). The PRB reviews and evaluates the initial appraisal of a senior executive’s performance by the supervisor, and makes recommendations to the Chair, EEOC, with respect to performance ratings, pay level adjustments and performance awards.

The following are the names and titles of executives appointed to serve as members of the SES PRB. Members will serve a 12-month term, which begins on October 4, 2010.

PRE Chair: Mr. James Neely, Director St. Louis District Office, Equal Employment Opportunity Commission.

Members:

Ms. Gwendolyn Reams, Associate General Counsel, Equal Employment Opportunity Commission;

Ms. Deidre Flippen, Director for Research, Information and Planning, Equal Employment Opportunity Commission;

Mr. John Rowe, Director, Chicago District Office, Equal Employment Opportunity Commission;

Ms. Tracey Sasser, Assistant General Counsel, Department of Education;

Ms. Linda Cruciani, Deputy General Counsel for Operations, Department of Housing and Urban Development.

Alternate: Mr. Michael Baldonado, Director, San Francisco District Office, Equal Employment Opportunity Commission.

Dated: October 6, 2010.

Jacqueline A. Berrien,
Chair.

[FR Doc. 2010-25782 Filed 10-14-10; 8:45 am]

BILLING CODE 6570-01-M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

October 6, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501-3520 Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before December 14, 2010. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or via Internet at Nicholas_A_Fraser@omb.eop.gov and to the Federal Communications Commission. To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1139.
Title: Residential Fixed Broadband Services Testing and Measurement.
Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; and business or other for-profit.

Number of Respondents: 11,016 respondents; 11,016 responses.

Estimated Time per Response: 1 hour for respondents based on a 10 minute initial sign-up for the panel, 30 minutes to connect and install the hardware appliance, and two 10-minute validation contacts to be conducted by the vendor over the course of the study period. The 16 ISP partners participating in the study is estimated at 200 hours per response per partner for all participation activities.

Frequency of Response: Biennial reporting requirement and third party disclosure requirement.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in the Broadband Data Improvement Act of 2008, Public Law 110–385, Stat 4096 § 103(c)(1).

Total Annual Burden: 14,200 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: This information collection affects individuals or households. However, the collection of personally identifiable information (PII) is not being collected, made available or accessible by the Commission but instead by third parties including SamKnows, a third party contractor, and ISP Partners.

Nature and Extent of Confidentiality: No personally identifying information (PII) will be transmitted to the Commission from the contractor as a matter of vendor policy. SamKnows maintains a series of administrative, technical, and physical safeguards to protect against the transmission of personally identifying information. At point of registration, individuals will be given full disclosure in a “privacy statement” highlighting what information will be collected. ISP Partners will receive personally identifying information about volunteers to confirm the validity of the information against their subscription records, but will be bound by a non-disclosure agreement that will maintain various administrative, technical and physical safeguards to protect the information and limit its use. ISP Partners providing support to the testing program will likewise be bound to the same series of administrative, technical and physical safeguards developed by SamKnows. In addition all third parties supporting the program directly will be

bound by a “Code of Conduct” to ensure all participate and act in good faith.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three-year clearance from them. The Commission had requested emergency processing for this revised collection on September 2, 2010. The Commission received OMB approval on October 4, 2010. Emergency OMB approvals are only granted for six months. Therefore, the Commission is now requesting approval of an extension of this information collection (no change in the reporting requirement or third party disclosure requirements) to keep the approval from lapsing.

The Broadband Data Improvement Act of 2008, Public Law 110–385, Stat 4096 § 103(c)(1) directs the Commission to collect information on the type of technology used to provide broadband to consumers, the price of such services, actual transmission speeds, and the reasons for non-adoption of broadband service.

This collection of information was necessary to complete research done for the Broadband Plan on key consumer issues including transparency and actual speeds and performance of broadband service.

This information collection was revised to respond to new requirements that were initially unforeseen. Recent surveys demonstrate a majority of consumers are not able to accurately report the broadband service information approved in the first collection approved on April 30, 2010.

In recent discussions, broadband service providers (ISPs) have also noted that certain technical characteristics of broadband service may vary region to region and such information may not be available from the consumer. ISP Partners have offered to partner with the FCC in the testing and measurement trial by verifying certain consumer information collected by SamKnows and by providing associated data not directly available from the consumer. This information is crucial for good sample selection and analysis of results.

The Commission’s Office of Engineering and Technology (OET), the Office of Strategic Planning and Policy Analysis (OSPPA) and the Consumer and Governmental Affairs Bureau (CGB) and other Commission entities will use the information collected under this study to assess what actual broadband speeds and performance consumers are currently receiving from providers. Our purpose is to measure the speed of broadband services provided by ISPs across service packages and

geographies, rather than assess the differences in broadband performance received by demographics. This assessment will help the Commission create standards for broadband measurements, assess the validity of ISP performance claims, and inform future steps to increasing transparency and consumer awareness of broadband service.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 2010–25926 Filed 10–14–10; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

October 6, 2010.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501–3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before December 14, 2010. If you anticipate that you will be submitting PRA comments but find it difficult to do so within the period of

time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or via Internet at Nicholas.A.Fraser@omb.eop.gov and to the Federal Communications Commission. To submit your PRA comments by e-mail, send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202-418-0214 or via the Internet at Judith.B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0484.

Title: Sections 4.1 and 4.2, and Part 4 of the Commission's Rules Concerning Disruptions to Communications (NORS).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local or tribal government.

Number of Respondents: 71 respondents; 139 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, 218, 219, 230, 256, 301, 302, 303, 403, and 621.

Total Annual Burden: 19,738 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality:

In accordance with 47 CFR 4.2 of the Commission's rules, reports under Part 4 are presumed confidential.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three-year clearance from them. The Commission is requesting approval of an extension of this information collection (no change in the reporting requirement). The Commission is reporting a significant increase of 10,100 hours in the total annual burden hours. This is due to a recalculation of our burden estimates and fewer respondents reporting information. The estimated number of respondents fluctuates because of the type of event to be reported and the location where it occurred.

In recognition of the critical need for rapid, full, and accurate information on

service disruptions that could affect homeland security, public health and safety, as well as the economic well-being of our Nation, and in view of the increasing importance of non-wireline communications in the Nation's communications networks and critical infrastructure, the Commission adopted rules requiring mandatory service disruptions reporting from all communications providers (cable, satellite, wireline and wireless) that provide voice and/or paging communications. As envisioned, the information collected pursuant to these rules has helped improve network reliability.

OMB Control Number: 3060-1094.

Title: Sections 27.14 and 27.1221, Licensing, Operation and Transition of the 2500-2690 MHz Band.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local or tribal government.

Number of Respondents: 2,500 respondents; 5,140 responses.

Estimated Time per Response: .50-2.25 hours.

Frequency of Response: On occasion and one-time reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 301, 303(f), 303(g), 303(r), 307, 308, and 316.

Total Annual Burden: 3,510 hours.

Total Annual Cost: \$302,667.

Privacy Act Impact Assessment: N/A.

Needs and Uses: The Commission will submit this revised information collection to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three-year clearance from them.

The Commission is reporting a program change decrease of 7,214 hours which is due to elimination of the pre-transition data request, the transition notice, the initiation plan, the post-transition notification and the transition plan because they relate to the transition of BRS and EBS licensees to the new band plan and these requirements have been met. The Commission is also reporting an adjustment decrease of 2,267 hours due to recalculation of all the remaining burden estimates.

The FCC adopted and released a Fourth Memorandum Opinion and Order (2008 Order), FCC 08-83, which adopted section 27.14(o) of the Commission's rules. That rule requires all Broadband Radio Service (BRS) and

Educational Broadband Service (EBS) licensees to make a showing of "substantial service" no later than May 1, 2011 on a license-by-license basis. The requirement was modified by the Third Report and Order (2010 Order), FCC 10-107, to require that licensees issue a new BRS license on or after November 6, 2009, and would have four years from the date of initial grant to provide substantial service. A licensee must demonstrate that it provided service which is sound, favorable and substantially above the level of mediocre service which might minimally warrant renewal.

The information relating to substantial service is used by the Commission staff to satisfy requirements for licensees to demonstrate substantial service at the time of license renewal. Without this information, the Commission would not be able to carry out its statutory responsibilities. The third party disclosure coordination requirements are necessary to ensure that licensees do not cause interference to each other and that licensees who undertake to transition to the new band plan receive reimbursement for eligible costs.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2010-25927 Filed 10-14-10; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget (OMB)

October 7, 2010.

SUMMARY: The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1995, Public Law 104-13. 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.

DATES: Persons wishing to comment on this information collection should submit comments by November 15, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of

Management and Budget (OMB), via fax at (202) 395-5167, or via the Internet at Nicholas_A_Fraser@omb.eop.gov, and to Nancy J. Brooks, (202) 418-2454 or via the Internet at Nancy.Brooks@fcc.gov, Federal Communications Commission (FCC). To submit your PRA comments by e-mail send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Nancy Brooks, (202) 418-2454 or via the Internet at Nancy.Brooks@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060-1139.

OMB Approval Date: 10/4/2010.

OMB Expiration Date: 4/30/2011.

Title: Residential Fixed Broadband Services Testing and Measurement.

Form No.: N/A.

Estimated Annual Burden: 11,016 responses; 14,200 total annual hours; 1 hour per response.

Obligation To Respond: Voluntary. Statutory authorities for this information collection are contained in the American Reinvestment and Recovery Act (ARRA) of 2009, Public Law 111-5 and the Broadband Data Improvement Act of 2008, Public Law 111-385.

Nature and Extent of Confidentiality: Yes. See Privacy Act Impact Assessment below.

Privacy Act Impact Assessment: Yes, however, no personally identifiable information (PII) will be transmitted to the Commission. SamKnows, Inc. maintains a series of administrative, technical and physical safeguards to protect against the transmission of personally identifying information. At point of registration, individuals will be given full disclosure, highlighting what information will be collected, and importantly, what information will not be collected.

Needs and Uses: The Commission has contracted with SamKnows, Inc. to measure the speeds and performance of a representative, cost-effective, statistically relevant sample of U.S. fixed broadband households across geographics, technologies and providers. This measurement will occur on an opt-in, voluntary basis. This representative sample will be used to create a baseline level of performance and measurements for the FCC. The third party measurement contractor will deploy testing devices to begin measurement, and these results will then be used to inform measurement standards for performance of broadband services, in support of the FCC-led National Broadband Plan.

This revised information collection responds to new requirements that were initially unforeseen in the SamKnows

Residential Fixed Broadband Services Testing and Measurement program. Recent surveys demonstrate a majority of consumers are not able to accurately report the broadband service information approved in the First Collection. Furthermore in recent discussions as part of this data collection effort, broadband internet service providers (ISPs) have indicated that certain technical characteristics of consumer broadband service may vary region to region and such details may not be fully known to the consumer. Relevant ISPs have offered to partner with the FCC in the testing and measurement trial by verifying certain customer information (ISP Partners) collected by SamKnows and by providing associated data not directly obtainable from the consumer. On September 2, 2010, the Commission requested emergency approval of the information collection requirements from the Office of Management and Budget (OMB). On October 4, 2010, the Commission received OMB approval.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2010-25925 Filed 10-14-10; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2918]

Petitions for Reconsideration of Action in Rulemaking Proceeding

September 23, 2010.

Petitions for Reconsideration have been filed in the Commission's Rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of these documents is available for viewing and copying in Room CY-B402, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) (1-800-378-3160). Oppositions to these petitions must be filed by November 1, 2010. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to oppositions must be filed within 10 days after the time for filing oppositions have expired.

Subject: In the Matter of Implementation of Section 224 of the Act (WC Docket No. 07-245)

A National Broadband Plan for our Future (GN Docket No. 09-51).

Number of Petitions Filed: 4.

Marlene H. Dortch,

Secretary.

[FR Doc. 2010-26059 Filed 10-14-10; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change The Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The following applicants filed AM or FM proposals to change the community of license: 1TV.COM, INC., Station KIKO, Facility ID 72477, BP-20100824ABA, From MIAMI, AZ, To SUPERIOR, AZ; AIRWAVES FOR JESUS, INC., Station NONE, Facility ID 176879, BMPED-20100831AAQ, From CRAIGSVILLE, WV, To WEBSTER SPRINGS, WV; ENTRAVISION HOLDINGS, LLC, Station KVVA-FM, Facility ID 1331, BPH-20100817ABA, From APACHE JUNCTION, AZ, To SUN LAKES, AZ; MEDIA MINISTRIES, INC., Station KLIC, Facility ID 22171, BP-20100903ABU, From MONROE, LA, To RICHWOOD, LA; PMB BROADCASTING, LLC, Station WKCN, Facility ID 54670, BPH-20100908ACE, From LUMPKIN, GA, To FORT BENNING SOUTH, GA; SOUTHWEST FM BROADCASTING CO., INC., Station KAHM, Facility ID 61510, BPH-20100813BHN, From PRESCOTT, AZ, To SPRING VALLEY, AZ.

DATES: Comments may be filed through December 14, 2010.

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

FOR FURTHER INFORMATION CONTACT: Tung Bui, 202-418-2700.

SUPPLEMENTARY INFORMATION: The full text of these applications is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC 20554 or electronically via the Media Bureau's Consolidated Data Base System, http://svartifoss2.fcc.gov/prod/cdbs/pubacc/prod/cdbs_pa.htm. A copy of this application may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-378-3160 or <http://www.BCPIWEB.com>.

Federal Communications Commission

James D. Bradshaw,

Deputy Chief, Audio Division, Media Bureau.

[FR Doc. 2010-25928 Filed 10-14-10; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. chapter 409 and 46 CFR part 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

ACS Logistics USA Inc. (NVO & OFF),
7 Elkridge Way, Manalapan, NJ 07726.

Officers: Snezana Pogosyan, Secretary (Qualifying Individual), Daniel Gleeson, President/Secretary.

Application Type: Add NVO Service.

Alto Air Freight, Inc. (NVO), 145 Hook Creek Boulevard, Bldg. B6 A, Valley Stream, NY 11581. Officers: Corey R. Morris, Vice President of Ocean management (Qualifying Individual), Andrienne Silver, President.

Application Type: QI Change.

Archer Logistics USA LLC (NVO), 6051 Kennedy Boulevard East, PhB, West New York, NJ 07093. Officers: Pape A. Ndoye, President (Qualifying Individual), Papa M. Cisse, Officer.

Application Type: New NVO License.

Averitt Express, Inc. (NVO & OFF), 1415 Neal Street, Cookeville, TN 38502-3166. Officers: Charles S. McGee, Vice President International Solutions (Qualifying Individual), Gary D. Sasser, President/CEO. Application Type: QI Change.

Bison International Inc. (NVO & OFF), 2251 Madiara Lane, Buffalo Grove, IL 60089. Officers: Winnie W. Wu, Vice President/Director (Qualifying Individual), Larry Y.R. Wu, President/CEO/Director. Application Type: New NVO & OFF License.

Braid Logistics (North America), Inc. (NVO), 5642 Shirley Lane, Houston, TX 77346. Officers: Michael Ng, Vice President of Marketing & Operations (Qualifying Individual), Shane

Watson, CEO. Application Type: QI Change and Name Change.
Capital Transportation Customs Clearance Services, Inc. (NVO & OFF), 6000 NW 97 Avenue, #9-10, Miami, FL 33178. Officers: Manuel G. Viegas, President (Qualifying Individual), Francisco A. Neves, Vice President. Application Type: License Transfer.
Cargo Brokers International, Inc. dba Martainer (NVO & OFF), 107 Forest Parkway, Suite 600, Forest Park, GA 30297. Officers: Carsten O. Steinmetz, Chief Executive Officer (Qualifying Individual), Goetz Steinmetz, President. Application Type: QI Change.

David A. Knott dba DAK Logistics Services (NVO), 1010 Bluejay Drive, Suisun City, CA 94585. Officer: David A. Knott, Owner (Qualifying Individual), Application Type: New NVO License.

Direct Parcel Service, CORP. dba DPS Cargo (NVO & OFF), 7701 NW 46 Street, Doral, FL 33166. Officers: Juan Monagas, Director (Qualifying Individual), Veronica Morales, Director. Application Type: QI Change.

EBM Export Services, LLC (NVO & OFF), 11100 S. Wilcrest Drive, Suite H, Houston, TX 77099. Officer: Benjamin E. Mbonu, Managing Member (Qualifying Individual), Application Type: New NVO & OFF License.

EnLog Strategic Services LLC (NVO & OFF), 363 N Sam Houston Parkway, #1100, Houston, TX 77060. Officers: Tracy Ball, Vice President (Qualifying Individual), Jonathan S. Blankenship, President. Application Type: New NVO & OFF License.

Intercontinental Forwarding USA, Corp. dba Expocoe Corp. (NVO & OFF), 1850 NW 84th Avenue, Suite 100, Doral, FL 33126. Officers: Byron Baez, Vice President (Qualifying Individual), Geovanny N. Coellar, President. Application Type: Trade Name Change.

ITO El Paso, International Transport Organization, Inc. (OFF), 9601 Carnegie Avenue, Suite 100, El Paso, TX 79925. Officers: Fritz Schult, Vice President (Qualifying Individual), George Koenigsmann, President/Director. Application Type: New OFF License.

Montero Express Cargo, Inc. (NVO), 7705 NW 29 Street, Suite 101, Doral, FL 33122. Officers: Enrique A. Montero, President (Qualifying Individual), Ricardo J. Valdez Peguero, Secretary. Application Type: New NVO License.

Movage, Inc. (NVO & OFF), 135 Lincoln Avenue, Bronx, NY 10454. Officers:

Traveler Schinz-DeVico, VP, International Sales (Qualifying Individual), Bajo Vujovic, President/Treasurer. Application Type: New NVO & OFF License.
North Star Container, LLC (NVO), 7400 Metro Boulevard, Suite 300, Edina, MN 55439. Officers: Shawn D. Steen, Assistant Vice President (Qualifying Individual), Guohe Mao, CEO. Application Type: QI Change.
Specialty Freight Services, Inc. (NVO & OFF), 2 Poulson Avenue, Essington, PA 19029. Officers: Erin N. Goodwin, Secretary (Qualifying Individual), William J. Colfer, President/Treasurer. Application Type: New NVO & OFF License.

Dated: October 8, 2010.

Karen V. Gregory,
Secretary.

[FR Doc. 2010-25935 Filed 10-14-10; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Request for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice and request for comment.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC is seeking public comments on its proposal to extend through December 31, 2013, the current PRA clearance for information collection requirements contained in its Consumer Product Warranty Rule. Those clearances expire on December 31, 2010.

DATES: Comments must be received on or before November 15, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form, by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Comments in electronic form should be submitted by using the following Web link: (<https://ftcpublic.commentworks.com/ftc/consumerwarrantypra2>) (and following the instructions on the Web-based form). Comments in paper form should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580, in the

manner detailed in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT:

Requests for copies of the collection of information and supporting documentation should be addressed to Allyson Himelfarb, Investigator, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Room H-286, 600 Pennsylvania Ave., NW., Washington, DC 20580, (202) 326-2505.

SUPPLEMENTARY INFORMATION:

Proposed Information Collection Activities

Under the PRA, 44 U.S.C. 3501-3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3), 5 CFR 1320.3(c).

On July 1, 2010, the FTC sought comment on the information collection requirements associated with the Rule Concerning Disclosure of Written Consumer Product Warranty Terms and Conditions (the Warranty Rule), 16 CFR part 701. No comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule (OMB Control No. 3084-0111). All comments should be filed as prescribed herein and must be received on or before November 15, 2010.

The Warranty Rule is one of three rules¹ that the FTC implemented pursuant to requirements of the Magnuson-Moss Warranty Act, 15 U.S.C. 2301 *et seq.* (Warranty Act or Act).² The Warranty Rule specifies the information that must appear in a written warranty on a consumer product costing more than \$15. The Rule tracks Section 102(a) of the Warranty Act,³ specifying information that must appear in the written warranty and, for certain disclosures, mandates the exact language that must be used.⁴ Neither the Warranty Rule nor the Act requires that a manufacturer or retailer warrant a consumer product in writing, but if they

choose to do so, the warranty must comply with the Rule.

Request for Comments

Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to "Warranty Rules: Paperwork Comment, FTC File No. P044403" to facilitate the organization of comments. Please note that your comment—including your name and your State—will be placed on the public record of this proceeding, including on the publicly accessible FTC Web site, at <http://www.ftc.gov/os/publiccomments.shtm>.

Because comments will be made public, they should not include any sensitive personal information, such as an individual'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. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential" as provided in Section 6(f) of the Federal Trade Commission Act (FTC Act), 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c).

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following Web link: <https://ftcpublic.commentworks.com/ftc/consumerwarrantypra2> (and following the instructions on the Web-based form). If this Notice appears at <http://www.regulations.gov>, you may also file an electronic comment through that Web site. The Commission will consider all comments that [regulations.gov](http://www.regulations.gov) forwards to it.

A comment filed in paper form should include the "Warranty Rules: Paperwork Comment, FTC File No. P044403" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, NW.,

Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

Comments on any proposed recordkeeping, or disclosure requirements that are subject to Paperwork Reduction Act review by the OMB should additionally be submitted via facsimile to OMB at (202) 395-5167 and addressed as follows: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Federal Trade Commission. Facsimile submission is preferred over U.S. postal mail delivery by the OMB, as the latter type of delivery is subject to delays due to heightened security precautions. Still, in case it is needed, the OMB mail address is: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503. The OMB requests that any comment filed in paper form be sent by courier or overnight service, if possible.

The FTC Act and other laws 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, whether filed in paper or electronic form. Comments received will be available to the public on the FTC's Web site, to the extent practicable, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC's Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.shtm>.

Warranty Rule Burden Statement:
Total annual hours burden: 127,000 hours, rounded to the nearest thousand.

In its 2007 submission to OMB, the FTC estimated that the information collection burden of including the disclosures required by the Warranty Rule was approximately 107,000 hours per year. Although the Rule's information collection requirements have not changed, this estimate increases the number of manufacturers subject to the Rule based on recent Census data. Nevertheless, because most

¹ The other two rules relate to the pre-sale availability of warranty terms and minimum standards for informal dispute settlement mechanisms that are incorporated into a written warranty.

² 40 FR 60168 (Dec. 31, 1975).

³ 15 U.S.C. 2302(a).

⁴ 40 FR 60168, 60169-60170.

warrantors would now disclose this information even if there were no statute or rule requiring them to do so, staff's estimates likely overstate the PRA-related burden attributable to the Rule. Moreover, the Warranty Rule has been in effect since 1976, and warrantors have long since modified their warranties to include the information the Rule requires.

Based on conversations with various warrantors' representatives over the years, staff has concluded that eight hours per year is a reasonable estimate of warrantors' PRA-related burden attributable to the Warranty Rule.⁵ This estimate takes into account ensuring that new warranties and changes to existing warranties comply with the Rule. Based on recent Census data, staff now estimates that there are 15,922 manufacturers covered by the Rule.⁶ This results in an annual burden estimate of approximately 127,376 hours (15,922 manufacturers × 8 hours of burden per year).

Total annual labor costs: \$16,941,000, rounded to the nearest thousand.

Labor costs are derived by applying appropriate hourly cost figures to the burden hours described above. The work required to comply with the Warranty Rule—ensuring that new warranties and changes to existing warranties comply with the Rule—requires a mix of legal analysis and clerical support. Staff estimates that half of the total burden hours (63,688 hours) requires legal analysis at an average hourly wage of \$250 for legal professionals,⁷ resulting in a labor cost of \$15,922,000. Assuming that the remaining half of the total burden hours requires clerical work at an average hourly wage of \$16, the resulting labor cost is approximately \$1,019,008. Thus, the total annual labor cost is approximately \$16,941,008 (\$15,922,000 for legal professionals + \$1,019,008 for clerical workers).

Total annual capital or other nonlabor costs: \$0.

The Rule imposes no appreciable current capital or start-up costs. As stated above, warrantors have already

⁵ FTC staff recently contacted two manufacturing associations—the Association of Home Appliance Manufacturers and the National Association of Manufacturers—but we have not received any additional information that further clarifies this estimate.

⁶ Because some manufacturers likely make products that are not priced above \$15 or not intended for household use—and thus would not be subject to the Rule—this figure is likely an overstatement.

⁷ Staff has derived an hourly wage rate for legal professionals based upon industry knowledge. The clerical wage rate used in this Notice is based on recent data from the Bureau of Labor Statistics National Compensation Survey.

modified their warranties to include the information the Rule requires. Rule compliance does not require the use of any capital goods, other than ordinary office equipment, which providers would already have available for general business use.

Willard K. Tom,
General Counsel.

[FR Doc. 2010-25983 Filed 10-14-10; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

5th Annual PHEMCE Stakeholders Workshop and BARDA Industry Day

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is pleased to announce the upcoming 5th Annual Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Stakeholders Workshop and BARDA Industry Day to be held January 10–12, 2011 at the Walter E. Washington Convention Center in Washington, DC. This annual PHEMCE event will bring together private- and public-sector stakeholders including: Federal Officials, International Governments, Industry, Healthcare Providers, First Responders, Community-Based Organizations, and other interested audiences. Attendees will have opportunities to participate in Medical Countermeasure focused forums on:

- Pre-Event Positioning of Medical Countermeasures.
- Emergency Planning for Vulnerable Populations.
- Industry Feedback on Contracting Issue.
- Medical Countermeasures Development: Expanding the Pipeline and Exploring Multi-Use Potential.
- BARDA Industry Day Presentations.

This free Workshop will also address current state of public health emergency medical countermeasure preparedness plans and opportunities to enhance national response capabilities. BARDA Industry Day provides a unique opportunity for biotechnology and pharmaceutical industry representatives to showcase their latest advances in vaccines, therapeutics, diagnostics, and platform technologies targeting chemical, biological, radiological, nuclear, and naturally emerging threats, including pandemic influenza.

DATES: The 5th Annual PHEMCE Stakeholders Workshop and BARDA Industry Day will be held January 10–12, 2011. Each day will begin at 9 a.m.

ADDRESSES: The Workshop will be held at the Walter E. Washington Convention Center, 801 Mount Vernon Place, NW., Washington, DC 20001.

Registration: There is no fee to attend; however, space is limited and registration is required. Registration and the preliminary agenda are available online at: <http://www.medicalcountermeasures.gov>.

FOR FURTHER INFORMATION CONTACT: L. Paige Rogers, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response at 330 Independence Ave., SW., Room G640, Washington, DC 20201, e-mail at BARDA@hhs.gov, or by phone at 202-260-0365.

Dated: September 16, 2010.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2010-26047 Filed 10-14-10; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-New; 30-day notice]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number,

OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

Proposed Project: ONC State HIE Performance Measures and Progress Report—OMB No. 0990-NEW—Office

of the National Coordinator for Health Information Technology.

Abstract: The purpose of the State Health Information Exchange Cooperative Agreement Program, as authorized by Section 3013 of the American Recovery and Reinvestment Act is to provide grants to States and Qualified State Designated Entities is to facilitate and expand the secure, electronic movement and use of health information among organizations according to national recognized

standards. As part of that project, States and Qualified State Designated Entities are required to provide biannual program progress reports and report on performance measures during the implementation phase of the cooperative agreement. This request is for those two data gathering requirements. The data collection will last four years, which is the duration of the project, and this request is for the data collection for the first three years of that project period.

ESTIMATED ANNUALIZED BURDEN TABLE

| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden hours |
|-------------------------------------|--|-----------------------|------------------------------------|---------------------------------------|--------------------|
| Evaluation performance measures ... | State government or Qualified State Designated Entity. | 56 | 2 | 175 | 19,600 |
| Program progress report | State government or Qualified State Designated Entity. | 56 | 2 | 8 | 896 |
| Total | | | | | 20,496 |

Terry Nicolosi,
 Director, Office of Resources Management;
 Office of the Chief Information Officer.
 [FR Doc. 2010-25917 Filed 10-14-10; 8:45 am]
BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-NEW; 30-day notice]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
 In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

Proposed Project: ONC State HIE State Plans—OMB No. 0990-NEW—Office of the National Coordinator for Health Information Technology.

Abstract: The purpose of the State Health Information Exchange Cooperative Agreement Program, as authorized by Section 3013 of the American Recovery and Reinvestment Act is to provide grants to States and Qualified State Designated Entities is to facilitate and expand the secure, electronic movement and use of health information among organizations according to national recognized standards. Section 3013 requires States and Qualified State Designated Entities to have approved State Plans, consisting of strategic and operational components, before funding can be used for implementation activities. The State Plans must be submitted to the National Coordinator for Health Information Technology during the first year of the project period in order to receive implementation funding through the cooperative agreement. Annual updates to the State plans will be required in the three remaining project periods. The data collection will last four years, which is the duration of the project, and this request is for the data collection for the first three years of that project period.

ESTIMATED ANNUALIZED BURDEN TABLE

| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden hours |
|--|--|-----------------------|------------------------------------|---------------------------------------|--------------------|
| State Plans (Strategic and Operational). | State Government or Qualified State Designated Entity. | 56 | 1 | 10,024 | 561,244 |

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden hours |
|---------------------------------------|--|-----------------------|------------------------------------|---------------------------------------|--------------------|
| Subsequent updates to the State Plan. | State Government or Qualified State Designated Entity. | 56 | 1 | 500 | 28,000 |
| Total | | | | | 589,244 |

Terry Nicolosi,
*Director, Office of Resources Management;
 Office of the Chief Information Officer.*
 [FR Doc. 2010-25918 Filed 10-14-10; 8:45 am]
BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Centers for Medicare & Medicaid Services

Delegation of Authorities

Notice is hereby given that I have delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS), or his or her successor, authorities vested in the Secretary under Section 6409(a) and (b) of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148, as amended hereafter, relating to the development of a Medicare self-referral disclosure protocol and the reduction of amounts due and owing under Section 1877(g) [42 U.S.C. 1395nn(g)] of the Social Security Act.

This delegation of authorities excludes the authority under Section 6409(c) of ACA to submit a report to Congress on the implementation of Section 6409.

This delegation of authorities granted herein may be re-delegated.

These authorities shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations.

I hereby affirm and ratify any actions taken by the Administrator, CMS, or his or her subordinates, which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

This delegation of authorities granted herein is effective immediately.

Authority: 44 U.S.C. 3101.

Dated: September 29, 2010.

Kathleen Sebelius,
Secretary.

[FR Doc. 2010-25976 Filed 10-14-10; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Medicaid Program: Implementation of Section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 for Adjustments to the Federal Medical Assistance Percentage for Medicaid Federal Matching Funds

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: For purposes of Title XIX (Medicaid) of the Social Security Act, the Federal Medical Assistance Percentage (FMAP), defined in section 1905(b) of the Social Security Act, for each State beginning with fiscal year 2006 is subject to adjustment pursuant to section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111-3. Section 614 provides for a recalculation of the FMAP disregarding identifiable significantly disproportionate employer pension or insurance fund contributions for a State. These contributions, when counted, increase State personal income and, by operation of the statutory formula to calculate the FMAP, would decrease the FMAP for the State. This final notice announces the methodology that the U.S. Department of Health and Human Services will use to determine the need for, and amount of, any such recalculation of the FMAP for a State.

A. Background

Section 1905(b) of the Social Security Act defines the Federal Medical Assistance Percentage (FMAP), which is used to determine the share of Federal matching funds paid to each State for medical assistance payments under an approved Medicaid State plan under Title XIX of the Social Security Act. These FMAP rates are also used to determine Federal matching fund rates for State expenditures for assistance payments under certain social service programs under Title IV of the Social Security Act and for child health assistance expenditures under the

Children's Health Insurance Program under title XXI of the Social Security Act. In other **Federal Register** issuances, we have addressed changes to these FMAP rates required under the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5).

This notice addresses adjustments to the FMAP rates that are applicable only to the Medicaid program and required by Section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). Section 614 specifies that certain significantly disproportionate employer pension or insurance fund contributions shall be disregarded when computing the per capita income used to calculate the FMAP. The statutory formula for calculating the FMAP is based on the ratio of the State's per capita income to the per capita income of the entire United States. Under this formula, States with higher per capita income levels could have lower FMAP rates than States with lower per capita income levels. Significantly disproportionate employer pension or insurance fund contributions increase State personal income and, by operation of the statutory formula, could result in lower FMAPs than if those contributions were disregarded. CHIPRA requires adjustments to the Fiscal Year 2006 (FY06) through Fiscal Year 2010 (FY10) Medicaid FMAP rates and to any future FMAP calculation.

A notice with comment on the proposed implementation of Section 614 was published in the **Federal Register** on June 7, 2010. Only one person sent in comments during the 30-day period.

B. Calculation of the FMAP Adjustment Under CHIPRA

Section 614 of CHIPRA requires that the Title XIX Medicaid FMAP shall be adjusted for any States that had significantly disproportionate employer pension and insurance fund contributions. A significantly disproportionate employer contribution is defined as any identifiable employer contribution towards pension or other employee insurance funds that is estimated to accrue to residents of such

State for a calendar year if the increase exceeds 25 percent of the total increase in State personal income. The personal income data set originally used in calculating FMAP rates shall be used for making this adjustment to the FMAP rates.

The required adjustment is a recalculation of the FMAP rate disregarding any significantly disproportionate employer pension or insurance fund contribution in computing the State per capita income, but not disregarding such contributions in computing the United States per capita income used in the FMAP calculation. Section 614(c) provides that in no case shall a State have its FMAP reduced because of the application of this disregard.

Section 614(b)(3) specifies a special adjustment for negative growth in State personal income. In that instance, for the purposes of calculating the FMAP for a calendar year, an employer pension and insurance fund contribution shall be disregarded to the extent that it exceeds 125 percent of the amount of employer contribution in the previous calendar year. The methodology to implement this provision will be addressed in a future **Federal Register** notice.

C. Analysis of and Responses to Comments

In response to the June 2010 proposed regulation, we received correspondence from one commenter. The commenter posed several questions and suggestions.

Application of FMAP Adjustment

Comment: The commenter asked if HHS anticipates the adjustment applying to only one particular State or is there a reasonable expectation that other States may qualify? In addition, the commenter asked whether HHS will provide guidance to States in the form of thresholds above which a State may determine that a review of employer contributions is warranted for a potential FMAP adjustment.

Response: Except for Louisiana with a negative growth in personal income in 2005, all other States had increases in State personal income of between \$359 million and \$1.4 billion or more during the 2003–2008 time period. A contribution attributed to a particular State's personal income of at least 25 percent of these amounts would be necessary to trigger an FMAP adjustment. At this time, HHS knows of only one disproportionate employer contribution, attributed to Michigan in 2003. HHS does not think it is likely that another employer contribution in

2003–2008 would be considered disproportionate, but does not rule out the possibility. It is possible, however, that additional States may qualify at any point in the future. HHS does not intend to issue guidance with each FMAP notice on a State's potential threshold where a review of its employer contributions may be warranted. States can determine for themselves using Department of Commerce Bureau of Economic Analysis (BEA) data, whether an employer's contribution would meet the threshold for triggering an FMAP adjustment.

Definition of Employer Pension and Insurance Fund Contribution

Comment: The commenter asked whether the definition of "employer pension and insurance fund contribution" is the same as the BEA definition.

Response: HHS intends to use the BEA definition: contributions consisting of employer payments (including payments-in-kind) to private pension and profit-sharing plans, publicly administered government employee retirement plans, private group health and life insurance plans, privately administered workers' compensation plans, and supplemental unemployment benefit plans, formerly called "other labor income".

Accounting for Employer's Contributions

Comment: The commenter asked if it is the intent of the methodology to identify single employers with disproportionate pension and insurance fund contributions. The commenter also asked whether contributions from any employer (public, private for-profit, private non-profit, self-employed, S Corporations, C corporations, LLCs, etc) are eligible.

Response: The legislation states that a significantly disproportionate employer pension and insurance fund contribution is any identifiable employer contribution meeting the threshold. HHS reads this language to refer to the contribution of a single employer. The legislation does not exclude any employer.

Adjustment for Negative Growth in State Income

Comment: The commenter asked whether the cumulative amount of contributions in excess of 125 percent from all such qualifying employers would be disregarded for the special adjustment for negative growth in State personal income.

Response: This comment concerns the special adjustment for negative growth

in State personal income, which is not covered in this notice. HHS intends to issue another notice on the special adjustment for negative growth in State personal income.

Acceptable Evidence Submission

Comment: The commenter suggested that it would be beneficial for HHS to describe in more detail what evidence of disproportionate employer pension and insurance fund contribution is acceptable and asked what methodology will be used to determine the amounts of employer contributions estimated to accrue to residents of a State.

Response: In order to give States as much flexibility as possible in the type of information that can be submitted to request an adjustment, HHS does not want to prescribe the specific type or format of their submission, but the information should be documented in such a way to permit effective review and verification. HHS will be using the same methodology employed by BEA which is based on a distribution of industry wages to allocate employer contributions to States.

Time Period for Adjustment and Data Submission

Comment: The commenter asked whether it is correct that there is no end date to this provision. The commenter believed that the time frame for submitting data for employer contributions made between 2003 and 2008 by the end of FY 2010 is unreasonable and that States should be given up to 4 years to supply information for future years. The commenter also asked how long the verification process will take in considering a request to adjust a State's FMAP and indicates that States would appreciate a response within their fiscal year.

Response: The commenter correctly noted that the legislation does not indicate an end date to this provision. HHS finds the commenter's suggestion for a longer time frame for submitting initial data for the years 2003 through 2008 reasonable. HHS therefore extends the time frame for submitting data for employer contributions made between 2003 and 2008 to the end of FY 2011. Similarly, HHS agrees to extend the time frame for submitting data from 2009 and beyond such that the deadline for submission of data from 2009 and beyond will be the end of the second fiscal year following the year end of the employer's annual financial statement that includes the disproportionate employer contribution.

Because it is not known what information a State may submit as

justification for an FMAP adjustment, we cannot predetermine how much time will be required to verify the information, but will review and verify a State's submission and request for an adjustment to its FMAP as expeditiously as possible.

D. Methodology Utilized in the Calculation of the Adjustment to the Medicaid FMAP

This Final Notice announces the methodology that the U.S. Department of Health and Human Services (HHS) will use in implementing the employer contribution disregard required by Section 614 of CHIPRA. The approach reflects the absence of a Federal source of reliable and timely data on pension and insurance contributions by individual employer and State.

We will use the BEA definition of pension and insurance contributions: contributions consisting of employer payments (including payments-in-kind) to private pension and profit-sharing plans, publicly administered government employee retirement plans, private group health and life insurance plans, privately administered workers' compensation plans, and supplemental unemployment benefit plans, formerly called "other labor income".

We will identify significantly disproportionate employer pension or insurance contributions for a State by reviewing contributions identified by the State. We believe that States may have greater access to timely and relevant data on such contributions than is available from Federal data sources. We would request that any State that believes an individual employer has made a significantly disproportionate employer or insurance contribution provide data on that individual employer contribution to HHS. The State may submit official audited financial statements for the employer for the year of the contribution (starting with the year 2003) and the prior year. If the State does not submit official audited financial statements for the employer, the State may submit other evidence that the increase in the employer's contribution is likely to exceed 25 percent of the increase in the State's personal income in that year.

After a State submits written notification that such a contribution occurred, HHS will verify the State's data. As part of this verification process, HHS will search the Security Exchange Commission (SEC) filings or the Internal Revenue Service (IRS) 5500 Annual Return/Report of Employee Benefit Plan database to find the employer's contributions for the relevant two-year period. If HHS is unable to verify the

State's submitted data, no FMAP adjustment will be made.

After the State's data for an employer is verified, HHS will allocate employer contributions in both years to the State according to the methodology used by the BEA. Under that methodology, employer contributions to pension and insurance funds are distributed according to State wages and salaries by the employer's industry subsector. Then, HHS will determine whether the State increase in the employer contribution exceeds the trigger of 25 percent of the increase in total State personal income.

If the employer contribution is significantly disproportionate, HHS will disregard the State-allocated contribution, *i.e.*, subtract it from the State's personal income in that year. HHS will calculate the FMAP adjustment for the State using the revised State per capita income based on the newly calculated State personal income. Since the FMAP calculation involves the average per capita income for three years, the FMAP adjustment will be calculated for each fiscal year affected by the State's revised per capita income. For instance, a significantly disproportionate employer contribution in 2003 would affect the FMAPs for FY06 (based on State per capita income for calendar years 2001, 2002, and 2003), FY07 (based on State per capita income for calendar years 2002, 2003, and 2004), and FY08 (based on State per capita income for calendar years 2003, 2004, and 2005).

States may submit data on disproportionate employer contributions made between 2003 and 2008 to HHS by the end of FY 2011. The deadline for 2009 and beyond will be the end of the second fiscal year following the year end of the employer's annual financial statement that includes the disproportionate employer contribution.

To summarize this methodology, after receipt of a State submission, HHS will verify the employer contributions from SEC filings or IRS 5500 reports for the year of the contribution and the prior year. If the employer contributions are verified, HHS will allocate the employer contributions for the State for both years and determine whether the State increase in the employer contribution exceeds the trigger of 25 percent of the increase in the State's personal income. If the employer contribution meets the definition of significantly disproportionate by exceeding the trigger, HHS will recalculate the FMAP rates for the corresponding fiscal years. The Centers for Medicare & Medicaid Services (CMS) will then calculate the

changes in Federal medical assistance payments resulting from the adjusted FMAP rates for the State's applicable fiscal years. If HHS is unable to verify the State's submitted data, then no FMAP adjustment will be made.

DATES: Effective Dates: This final notice is effective 30 days after publication and sets forth a methodology for adjusted percentages applicable under title XIX of the Social Security Act for fiscal years 2006 and beyond, beginning October 1, 2005.

FOR FURTHER INFORMATION CONTACT: Rose Chu or Thomas Musco, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-6870.

Dated: September 10, 2010 .

Kathleen Sebelius,
Secretary.

[FR Doc. 2010-25977 Filed 10-14-10; 8:45 am]

BILLING CODE 4210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10304 and CMS-10315]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate 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 function; (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.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Information

Collection Requirements and Supporting Information for Chronic Kidney Disease Surveys under the 9th Scope of Work; *Form Number:* CMS-10304 (OMB #: 0938-New); *Use:* The Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (DHHS) are requesting OMB clearance for the Chronic Kidney Disease (CKD) Partner Survey and the Chronic Kidney Disease (CKD) Provider Survey. The Prevention CKD Theme is a component of the Prevention Theme of the Quality Improvement Organization (QIO) Program's 9th Scope of Work (SOW). The statutory authority for this scope of work is found in Part B of Title XI of the Social Security Act (the Act) as amended by the Peer Review Improvement Act of 1982. The Act established the Utilization and Quality Control Peer Review Organization Program, now known as the Quality Improvement Organization (QIO) Program.

The goal of the Prevention CKD Theme is to detect the incidence, decrease the progression of CKD, and improve care among Medicare beneficiaries through provider adoption of timely and effective quality of care interventions; participation in quality incentive initiatives; beneficiary education; and key linkages and collaborations for system change at the state and local level. In addition to improving the quality of care for the elderly and frail-elderly, this Theme aims to reduce the rate of Medicare entitlement by disability through the delay and prevention of end-stage renal disease (ESRD); thus resulting in higher quality care and significant savings to the Medicare Trust Fund.

The CKD Partner Survey constitutes a new information collection to be used by CMS to obtain information on how QIO collaboration with partners facilitates systems change within the QIO's respective state. The CKD Partner Survey will be a census administered to 350 collaborative partners in the 9th SOW. The CKD Partner Survey will be administered via telephone. Responses will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface. The results of the survey shall be used for inpatient quality indicators (IQI) by the QIO. CMS will also use the results to assess how partner organizations and their perspective of the QIO's role are implementing system change.

Similarly, the CKD Provider Survey constitutes a new information collection to be used by CMS to obtain information on how QIO collaboration with physician practices facilitates systems

change within the QIO's respective state. The CKD Provider Survey will be administered via telephone and the Web. Responses collected by phone will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface. Responses collected by Web will be housed on a secure server and database. The results of the survey shall be used for inpatient quality indicators (IQI) by the QIO. CMS will also use the results to assess how physicians' practices and their perspective of the QIO's role are implementing system change. *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for profit institutions; *Number of Respondents:* 1,350; *Total Annual Responses:* 1,350; *Total Annual Hours:* 337.5. (For policy questions regarding this collection contact Robert Kambic at 410-786-1515. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: New collection; *Title of Information Collection:* Patient Safety Survey Under the 9th Scope of Work: Nursing Home in Need (NHIN) *Use:* The Centers for Medicare & Medicaid Services (CMS) is requesting OMB clearance for the Nursing Homes in Need (NHIN) Survey. The NHIN is a component of the Patient Safety Theme of the Quality Improvement Organization (QIO) Program's 9th Scope of Work (SOW). The statutory authority for this scope of work is found in Part B of Title XI of the Social Security Act (the Act) as amended by the Peer Review Improvement Act of 1982. The Act established the Utilization and Quality Control Peer Review Organization Program, now known as the Quality Improvement Organization (QIO) Program.

The QIO in each State will provide special technical assistance to a small number of nursing homes in need of assistance with quality improvement efforts. This special technical assistance will be for the QIO to conduct a root cause analysis (RCA) with one nursing home in its state per year (three over three years). Under this component, it is expected that within the first quarter of the contract period, CMS will assign one nursing home to each QIO. The determination of which nursing homes are eligible under this component will be made by CMS. Some of these facilities may meet criteria for Special Focus Facilities (SFF). The intent of this component is that each State QIO will work with three nursing homes over the three-year contract period; these assignments are expected to be spaced out so that each State QIO will get one

nursing home assigned approximately every 12 months.

The NHIN Survey is a new information collection to be used by CMS to obtain information on nursing home satisfaction with technical assistance strategies delivered as a component of the NHIN. The NHIN Survey will be a census of 53 nursing homes working with their respective QIOs. The survey will be conducted one time for each of the nursing homes assisted in the first two years under the 9th SOW and it will be conducted twice with nursing homes assisted in the third year. The information collected through this survey will allow CMS to help focus the NHIN task to maximize the benefit to participating nursing homes. The NHIN Survey will be administered via telephone by trained and experienced interviewers. Responses will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface.

The NHIN Survey will include questions to determine if the QIO has conducted a root cause analysis and developed an action plan. These will be followed by questions about their satisfaction with the QIO and their perceived value of the QIO's assistance. The NHIN Survey will address the following:

- Background information;
- Current work—*information and assessment*;
- Satisfaction with QIOs;
- Value of QIO assistance;
- Sources of information; and
- Respondent comments.

All survey protocol and correspondence will be translated into Spanish and bi-lingual telephone interviewers will be used as needed. *Form Number:* CMS-10315 (OMB #: 0938-New); *Frequency:* Occasionally; *Affected Public:* Businesses and other for-profit and not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 106; *Total Annual Hours:* 17.5 hours (years 1 and 2), 35 hours (year 3). (For policy questions regarding this collection contact Bob Kambic 410-786-1515. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *November 15, 2010*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, e-mail: *OIRA_submission@omb.eop.gov*.

Dated: *October 8, 2010*.

Martique Jones,

Director, Regulations Development Division—B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-25943 Filed 10-14-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-153 and CMS-10152]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate 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.

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicaid Drug Utilization Review (DUR) Annual Report; *Use:* The DUR program is required to assure that prescriptions are appropriate, medically necessary and are not likely to result in adverse medical results. Each State DUR program must consist of prospective drug use review, retrospective drug use review, data assessment of drug use

against predetermined standards, and ongoing educational outreach activities. In addition, States are required to submit an annual DUR program report that includes a description of the nature and scope of State DUR activities as outlined in the statute and regulations. Over the years, technology has changed as has the practice of the pharmacy. Therefore, CMS has revised the old survey vehicle to more fully address the current practices and areas of concern with the Medicaid Pharmacy Programs. *Form Number:* CMS-R-153 (OMB#: 0938-0659); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 20,298. (For policy questions regarding this collection contact Madlyn Kruh at 410-786-3239. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Using NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum # CAG-00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF-18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the CMS determines meet specified standards and address the specified research questions.

To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of

clinical criteria specific to each solid tumor. The statutory authority for this policy is section 1862(a)(1)(E) of the Social Security Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of NaF-18 PET to beneficiaries and for use in future clinical decision making. *Form Number:* CMS-10152 (OMB#: 0938-0968); *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084. (For policy questions regarding this collection contact Stuart Caplan at 410-786-9564. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *December 14, 2010*:

1. *Electronically.* You may submit 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) 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.

Dated: October 8, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-25934 Filed 10-14-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1561, CMS-R-308, CMS-10335 and CMS-R-53]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506l(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate 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 function; (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.

1. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Health Insurance Benefit Agreement; **Use:** Applicants to the Medicare program are required to agree to provide services in accordance with Federal requirements. The CMS-1561 is essential for CMS to ensure that applicants are in compliance with the requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval. **Form Number:** CMS-1561 (OMB#: 0938-0832); **Frequency:** Yearly; **Affected Public:** Private Sector: Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 3,000; **Total Annual Responses:** 3,000; **Total Annual Hours:** 500. (For policy questions regarding this collection contact JoAnn Perry at 410-786-3336. For all other issues call

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Children's Health Insurance Program; **Use:** States are required to submit title XXI plans and amendments for approval by the

Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. States are also required to submit State expenditure and statistical reports, annual reports and State evaluations to the Secretary as outlined in title XXI of the Social Security Act. **Form Number:** CMS-R-308 (OMB#: 0938-0841); **Frequency:** Yearly, Quarterly, Once and/or Occasionally; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 1,114,124 **Total Annual Hours:** 864,973. (For policy questions regarding this collection contact Nancy Goetschius at 410-786-0707. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: New collection; **Title of Information Collection:** Current State Practices Related to Payments to Providers for Health Care- Acquired Conditions; **Use:** The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), enacted March 23, 2010 includes provisions prohibiting Federal Financial Participation to States for payments for health care-acquired conditions (HCACs). Section 2702(a) specifically requires that the Secretary identify current State practices that prohibit payment for HCACs and incorporate those practices or elements of those practices which she determines appropriate for application to the Medicaid program. In accordance with section 2702(a) of the Affordable Care Act, CMS is issuing this survey to States to obtain information on current State Medicaid practices for prohibiting payments for HCACs. **Form Number:** CMS-10335 (OMB#: 0938-New); **Frequency:** Once; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 50 **Total Annual Responses:** 50; **Total Annual Hours:** 50 (For policy questions regarding this collection contact Venesa Day at 410-786-8281. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Imposition of Cost Sharing Charges under Medicaid and Supporting Regulations in 42 CFR 447.53; **Use:** The purpose of this collection is to ensure that States impose normal cost sharing charges upon categorically and medically needy individuals as allowed by law and implementing regulations. States must identify in their State plan the service for which the charge is made, the amount of the charge, the basis for

determining the charge, the basis for determining whether an individual is unable to pay the charge and the way in which the individual will be identified to providers, and the procedures for implementing and enforcing the exclusions from cost sharing. **Form Number:** CMS-R-53 (OMB#: 0938-0429); **Frequency:** Occasionally; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 2; **Total Annual Hours:** 20. (For policy questions regarding this collection contact Barbara Washington at 410-786-9964. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *November 15, 2010*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: *October 8, 2010*.

Michelle Shortt,
Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-25932 Filed 10-14-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-11-0728]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington,

DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The National Electronic Disease Surveillance System (NEDSS) (OMB Number 0920-0728 exp. 2/28/2011)—Extension—National Center for Public Health Informatics (NCPHI), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is responsible for the dissemination of nationally notifiable diseases information and for monitoring and reporting the impact of epidemic influenza on mortality, Public Health Services Act (42 U.S.C. 241). Since April 1984, CDC National Center for Public Health Informatics Epidemiology Program Office (EPO) began working with the Council of State and Territorial Epidemiologists (CSTE) to demonstrate the efficiency and effectiveness of computer transmission of surveillance data between CDC and the State health departments.

By 1989, all 50 States were using this computerized disease surveillance system, which was then renamed the National Electronic Telecommunications System for Surveillance (NETSS) to reflect its

national scope (OMB numbers 0920-0447 and 0920-0007).

Beginning in 1999, CDC, Epidemiology Program Office (EPO) worked with CSTE, State and local public health system staff, and other CDC disease prevention and control program staff to identify information categories and information technology standards to support integrated disease surveillance. That effort is now focused on development and completion of the National Electronic Disease Surveillance System (NEDSS), coordinated by CDC's National Center for Public Health Informatics, Division of Integrated Surveillance Systems and Services (DISSS).

States will continue to use portions of NETSS to transmit data to CDC. One of the reasons for providing NETSS to NEDSS data mapping is to identify what data elements in NETSS correspond to data elements in NEDSS. Those elements mapped from NETSS to NEDSS were collected in OMB number 0920-0007.

NEDSS will electronically integrate and link together a wide variety of surveillance activities and will facilitate more accurate and timely reporting of disease information to CDC and State and local health departments. Consistent with recommendations supported by our State and local

surveillance partners and described in the 1995 report, *Integrating Public Health Information and Surveillance Systems*, NEDSS includes data standards, an Internet based communications infrastructure built on industry standards, and policy-level agreements on data access, sharing, burden reduction, and protection of confidentiality.

To support NEDSS, CDC has developed an information system, the NEDSS Base System (NBS), which uses NEDSS technical and information standards. The NBS is currently deployed to 16 States, including AL, AR, ID, MD, ME, MT, NE, NM, NV, RI, SC, TN, TX, VA, VT, and WY.

CDC is requesting a three-year OMB clearance extension of collecting the NEDSS data. The table below outlines the annualized burden which consists of two components. The first component is "weekly reporting" (52 weeks annually). The second component is an end of year report titled "annual reporting". The two components collectively represent the estimated annualized hours for the submitting jurisdictions.

There are no costs to respondents other than their time. The total estimated annual burden hours for the Weekly Morbidity Reports and the Annual Summary Report is 9,384.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|-------------------------|-----------------------|------------------------------------|--|
| Weekly Reporting | | | |
| States | 50 | 52 | 3 |
| Territories | 5 | 52 | 1.5 |
| Cities | 2 | 52 | 3 |
| Annual Reporting | | | |
| States | 50 | 1 | 16 |
| Territories | 5 | 1 | 10 |
| Cities | 2 | 1 | 16 |

Dated: October 7, 2010.

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010-25916 Filed 10-14-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning

opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information

are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2011 National Survey on Drug Use and Health (OMB No. 0930-0110)—Revision

The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The survey is used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The survey is also used to collect information on mental health problems and the utilization of substance abuse and mental health services. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

The 2011 NSDUH will continue conducting a follow-up clinical interview with a subsample of approximately 1,500 respondents. The design of this study is based on the recommendations from a panel of expert consultants convened by the Center for Mental Health Services (CMHS), SAMHSA, to discuss mental health surveillance data collection strategies.

The goal is to create a statistically sound measure that may be used to estimate the prevalence of Serious Mental Illness (SMI) among adults (age 18+).

For the 2011 NSDUH, no questionnaire changes are proposed.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2011 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia.

Because the NSDUH collects data on substance use, mental health and the utilization of substance abuse and mental health services, it is an appropriate and convenient vehicle to measure the impact of the Deepwater Horizon oil spill on residents of that region. Therefore, SAMHSA is planning to expand the NSDUH by oversampling the geographic region impacted by the oil spill. The current NSDUH sample design will be implemented and an oversampling method that results in an additional 2,000 completed interviews in the gulf coast region will be employed. The additional interviews will be concentrated in the coastal counties of Alabama, Florida, Louisiana, and Mississippi. All survey instruments and protocols will be identical for this additional sample. The total number of respondents for the 2011 NSDUH will be 69,500, or 2,000 cases more than the planned sample size for 2010.

Though there will be some increase in the sample for all four states involved in the Deepwater Horizon event (Alabama, Florida, Louisiana, and Mississippi), specific counties in the gulf coast region were chosen for focused oversampling. These counties were chosen based on the following criteria:

- Claims activity to BP for economic and related health needs;

- County involvement with Department of Education and Administration for Children and Families programming; and
- State assessment of impacted counties based on consultation with SAMHSA during the preparation of aid applications.

COUNTIES DESIGNATED AS THE MOST AFFECTED AREAS

| State name | County/parish name |
|-------------------|--------------------|
| Alabama | Baldwin |
| Alabama | Clarke |
| Alabama | Escambia |
| Alabama | Mobile |
| Alabama | Monroe |
| Alabama | Washington |
| Florida | Bay |
| Florida | Escambia |
| Florida | Franklin |
| Florida | Gulf |
| Florida | Okaloosa |
| Florida | Santa Rosa |
| Florida | Wakulla |
| Florida | Walton |
| Louisiana | Iberia |
| Louisiana | Jefferson |
| Louisiana | Lafayette |
| Louisiana | Lafourche |
| Louisiana | Orleans |
| Louisiana | Plaquemines |
| Louisiana | St. Bernard |
| Louisiana | St. Martin |
| Louisiana | St. Mary |
| Louisiana | St. Tammany |
| Louisiana | Terrebonne |
| Louisiana | Vermilion |
| Mississippi | George |
| Mississippi | Hancock |
| Mississippi | Harrison |
| Mississippi | Jackson |
| Mississippi | Pearl River |
| Mississippi | Stone |

The total annual burden estimate is shown below:

| Instrument | Number of respondents | Responses per respondent | Hours per response | Total burden hours | Hourly wage rate | Annualized hourly costs |
|--|-----------------------|--------------------------|--------------------|--------------------|------------------|-------------------------|
| Household Screening | 196,720 | 1 | 0.083 | 16,328 | \$14.64 | \$239,042 |
| Interview | 69,500 | 1 | 1.000 | 69,500 | 14.64 | 1,017,480 |
| Clinical Follow-up Certification | 90 | 1 | 1.000 | 90 | 14.64 | 1,318 |
| Clinical Follow-up Interview | 1,500 | 1 | 1.000 | 1,500 | 14.64 | 21,960 |
| Screening Verification | 5,560 | 1 | 0.067 | 373 | 14.64 | 5,461 |
| Interview Verification | 10,425 | 1 | 0.067 | 698 | 14.64 | 10,219 |
| Total | 196,810 | | | 88,489 | | 1,295,480 |

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 AND e-mail a copy to *summer.king@samhsa.hhs.gov*. Written comments should be received within 30 days of this notice.

Dated: October 8, 2010.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2010–26077 Filed 10–14–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Block Grant Reporting Requirements—ACF–700.

OMB No.: 0980–0241.

Description: The Child Care and Development Fund (CCDF) report requests annual Tribal aggregate information on services provided through the CCDF, which is required by the CCDF Final Rule (45 FR parts 98 and

99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services. The CCDF statute and regulations also require TLAs to submit a supplemental narrative as part of the ACF–700 report. This narrative describes child care activities and actions in the TLA’s service area. Information from the ACF–700 and supplemental narrative report will be included in the Secretary’s Report to Congress, as appropriate, and will be shared with all TLAs to inform them of CCDF-funded activities in other Tribal programs.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| ACF–700 Report | 260 | 1 | 38 | 9,880 |

Estimated Total Annual Burden Hours: 9,880

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Dated: October 12, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–26052 Filed 10–14–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 4, 2010, pages 46945–6, and allowed 60-days for public comment. Only one comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. *Type of Information Request:* Renewal (OMB No. 0925–

0493). *Need and Use of Information Collection:* The study, MESA, is identifying and quantifying factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE–99–11–08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. *Frequency of response:* Once per CVD event. *Affected public:* Individuals. *Types of Respondents:* Physicians and selected proxies of individuals recruited for MESA. The annual reporting burden is as follows: *Estimated Number of Respondents:* 74; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 0.20; and *Estimated Total Annual Burden Hours Requested:* 14.7. The annualized cost to respondents is estimated at: \$500. There are no capital, operating, or maintenance costs to report.

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---------------------|---------------------------------|--|-----------------------------------|---|
| Physicians | 17 | 1.0 | 0.20 | 3.4 |
| Proxies | 57 | 1.0 | 0.20 | 11.3 |
| Total | 74 | 1.0 | 0.20 | 14.7 |

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Diane Bild, Division of Cardiovascular Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10122, MSC #7936, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0457 or E-mail your request, including your address to: bildd@nhlbi.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Suzanne Freeman,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2010-26030 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0380]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,

Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 17, 2010 (75 FR 12758), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0523. The approval expires on August 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-25975 Filed 10-14-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Office of Intramural Training & Education Application

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Intramural Training & Education, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 20, 2010 (Vol. 75, No. 138 on pages 42097-42098) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: NIH Office of Intramural Training & Education Application. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* The Office of Intramural Training & Education (OITE) administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the National Institutes of Health Intramural Research Program (NIH-IRP) to facilitate develop into future biomedical scientists. The proposed information collection is necessary in order to determine the eligibility and quality of potential awardees for traineeships in these programs. The applications for admission consideration include key areas such as: Personal information, eligibility criteria, contact information, student identification number, training program selection, scientific discipline interests, educational history, standardized examination scores, reference information, resume

components, employment history, employment interests, dissertation research details, letters of recommendation, financial aid history, sensitive data, future networking contact, travel information, as well as feedback questions about interviews and application submission experiences. Sensitive data collected on the applicants, race, gender, ethnicity and recruitment method, are made available only to OITE staff members or in aggregate form to select NIH offices and are not used by the admission

committee for admission consideration; optional to submit.
 Over the last several years the OITE has used three OMB Clearance Numbers for the collection of applications for the training programs. To improve announcement of all training programs and lessen the burden of applicants, the OITE proposes to merge the following:
 • 0925–0299—NIH Intramural Research Training Award, Program Application
 • 0925–0438—Undergraduate Scholarship Program (UGSP)
 • 0925–0501—Graduate Student Training Program Application

Renewing 0925–0299 OMB Clearance Number with the new name “Office of Intramural Training & Education Application”.

Frequency of Response: On Occasion.
Affected Public: Individuals seeking intramural training opportunities and references for these individuals. *Type of Respondents:* Students, post-baccalaureates, technicians, graduate students, and post-doctorates. There are no capital costs, operating costs, and/or maintenance costs to report.

The annual reporting burden is displayed in the following table:

ESTIMATES OF HOUR BURDEN

| Program | Estimated number of respondents | Estimated number of responses annually per respondents | Average burden hours per response | Estimated total annual burden hours |
|---|---------------------------------|--|-----------------------------------|-------------------------------------|
| Summer Internship Program in Biomedical Research (SIP) | 8,500 | 1 | 0.75 | 6,375.0 |
| Biomedical Engineering Summer Internship Program (IBESIP) | 100 | 1 | 0.75 | 75.0 |
| Post-baccalaureate Intramural Research Training Award | 2,300 | 1 | 0.75 | 1,725.0 |
| NIH Academy | 550 | 1 | 0.75 | 412.5 |
| Community College Summer Enrichment Program (CCSEP) | 125 | 1 | 0.75 | 93.8 |
| Technical Intramural Research Training Award | 140 | 1 | 0.75 | 105.0 |
| Graduate Partnerships Program (GPP) | 600 | 1 | 0.75 | 450.0 |
| Post-Doctorate Fellowship Program | 2,050 | 1 | 0.75 | 1,537.5 |
| National Graduate Student Research Festival (NGSRF) | 825 | 1 | 0.75 | 618.8 |
| Undergraduate Scholarship Program (UGSP) | 300 | 1 | 0.75 | 225.0 |
| Alumni Database | 1,900 | 1 | 0.75 | 1,425.0 |
| Recommendations for All Programs | 35,705 | 1 | 0.25 | 8,926.3 |
| Supplemental Documents for Application | 14,540 | 1 | 0.75 | 10,905.0 |
| Feedback Questions | 53,095 | 1 | 0.25 | 13,273.8 |
| Totals | 120,730 | | | 46,147.5 |

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response

time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA* submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia Wagner, Director of Admissions & Registrar, Office of Intramural Training & Education, National Institutes of Health, 2 Center Drive: Building 2/2E06, Bethesda, Maryland 20892–0234, or call 240–476–3619 or e-mail your request, including your address to: wagnerpa@od.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 5, 2010.

Michael M. Gottesman,
 Deputy Director of Intramural Research,
 National Institutes of Health.

[FR Doc. 2010–25708 Filed 10–14–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Epidemiologic Survey on Alcohol and Related Conditions—III

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of

Management and Budget (OMB) for review and approval.

Proposed Collection: Title: National Epidemiologic Survey on Alcohol and Related Conditions—III. Type of Information Collection Request: NEW. Need and Use of Information Collection: This study will determine the prevalence of alcohol use patterns and alcohol use disorders and their associated disabilities in a representative sample of adults in the United States population. The primary

objectives of this study are to: (1) Understand the relationships between alcohol use patterns and alcohol use disorders and their related psychological and medical disabilities with a view toward designing more effective treatment, prevention and intervention programs; (2) identify subgroups at high risk for alcohol use disorders that are complicated by associated disabilities; (3) understand treatment utilization, unmet treatment need, barriers to treatment, health

disparities, and economic costs of alcohol use disorders and their associated disabilities; and (4) identify environmental and genetic risk factors and their interactions that are associated with harmful consumption patterns and alcohol use disorders and their associated disabilities. *Frequency of Response: On occasion. Affected Public: Individuals. Type of Respondents: Adults. Estimated Total Annual Burden:*

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---------------------|---------------------------------|--|-----------------------------------|---|
| Adults | 44,900 | 1 | 1.0 | 44,900 |
| Adults | 1,700 | 2 | 1.7 | 2,890 |
| Total | | | | 47,790 |

The annualized cost to respondents is estimated to be \$936,684.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function 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, including the validity of the methodology and assumptions used; (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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instrument, contact Dr. Bridget Grant, Chief, Laboratory of Epidemiology and Biometry, DICBR, NIAAA, NIH, 5635 Fishers Lane, Room 3077, Rockville, MD 20852, or call non-toll-free number 301-443-7370 or e-mail your request, including your address, to: Bgrant@willco.niaaa.nih.gov.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 60-days of the date of this publication.

Dated: October 7, 2010.

Keith Lamirande,
Acting Executive Officer, NIAAA, National Institutes of Health.

[FR Doc. 2010-26022 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 materials, 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 on Drug Abuse Special Emphasis Panel, NIDA Basic Science Conference Grant (R13) Review.

Date: October 27, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive, Blvd., Bethesda, MD 20892-8401, 301-402-6626, gm145a@nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Treatment and Services Use.

Date: October 28, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jose F. Ruiz, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive, Blvd., Bethesda, MD 20892, 301-451-3086, ruizjff@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Initial Review Group, NIDA-K Conflicts Special Emphasis Panel.

Date: November 3, 2010.

Time: 5:30 p.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Eliane Lazar-Wesley, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive, Boulevard, Bethesda, MD 20892-8401, 301-451-4530, elazarwe@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA Research Education and Science Education Program Review (R25).

Date: November 10, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401, 301-402-6626, gm145a@nih.gov.

Name of Committee: National Institute on Drug Abuse Initial Review Group, P50 Centers Review.

Date: February 22-25, 2011.

Time: 8:30 a.m. to 5 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: Eliane Lazar-Wesley, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, 301-451-4530, elazarwe@nida.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26025 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business; Cancer Drug Development and Therapeutics.

Date: November 15-16, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: John Firrell, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301-435-2598, firrellj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Risk Prevention and Health Behavior.

Date: November 18, 2010.

Time: 2 p.m. to 4 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: Stacey FitzSimmons, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, 301-451-9956, fitzsimmonss@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Risk Prevention and Health Behavior.

Date: November 19, 2010.

Time: 2 p.m. to 3 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: Stacey FitzSimmons, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, 301-451-9956, fitzsimmonss@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; NeuroAIDS and Other End-Organ Diseases Study Section.

Date: December 1, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree O'Hare Airport Hotel, 5460 North River Road, Rosemont, IL 60018.

Contact Person: Rossana Berti, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, MSC 7846, Bethesda, MD 20892, 301-402-6411, bertiros@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 10-219: AIDS International Training and Research Program.

Date: December 3-4, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7808, Bethesda, MD 20892, 301-435-1034, beitinsi@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: October 6, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26028 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Career Development, Research Training & Pathways to Independence Review.

Date: October 29, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Contact Person: Charles H. Washabaugh, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Suite 800, Bethesda, MD 20817, 301-594-4952, washabac@mail.nih.gov.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases, Special Emphasis Panel. Accelerating Research Translation Review.

Date: November 8, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Charles H. Washabaugh, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Suite 800, Bethesda, MD

20817, 301-594-4952,
washabac@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 8, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26070 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Initial Review Group; Minority Programs Review Subcommittee B.

Date: November 8, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Rebecca H. Johnson, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301-594-2771, johnsonrh@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26037 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; 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 Director's Council of Public Representatives.

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: Director's Council of Public Representatives.

Date: November 5, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: The Council will discuss opportunities to increase public input and participation. Further information will be available on the COPR Web site.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Sheria Washington, Executive Secretary/Outreach Program Specialist, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 1 Center Drive, Room 331, Bethesda, MD 20892, 301-594-4837, Sheria.Washington@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: <http://www.copr.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research

Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS).

Dated: October 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26036 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, R13 Conference Grant Review.

Date: November 8-9, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Bratin K. Saha, PhD, Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8041, Bethesda, MD 20892, (301) 402-0371, sahab@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Early Therapeutics Development with Phase II Emphasis.

Date: December 1-2, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Lalita D. Palekar, PhD, Scientific Review Officer, Special Review

and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7141, Bethesda, MD 20892, 301-496-7575, palekarl@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Community/Minority Based Clinical Oncology Program (CCOP)(U10).

Date: December 6, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Ellen K. Schwartz, PhD, Scientific Review Officer, Special Review & Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8055B, Bethesda, MD 20892-8329, 301-594-1215, schwarel@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: October 8, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26035 Filed 10-14-10; 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; 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 materials, 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications—Biosciences.

Date: October 28, 2010.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ranga Srinivas, PhD, Chief, Extramural Project Review Branch, EPRB, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Bethesda, MD 20892, 301-451-2067, srinivar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: October 7, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26034 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Neurotechnology and Neurogenetics.

Date: November 8, 2010.

Time: 11 a.m. to 1 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: Joseph G. Rudolph, PhD, Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892. 301-408-9098. josephru@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of Musculoskeletal, Oral, and Skin Systems.

Date: November 9, 2010.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Mayflower Renaissance Washington, DC Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Abdelouahab Aitouche, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7812, Bethesda, MD 20892. 301-435-2365. aitouchea@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR09-129: MLPCN High Throughput Screening Assays for Drug Discovery.

Date: November 12, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892. 301-408-9971. fanpcommat@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: October 7, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26033 Filed 10-14-10; 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 National Cancer Institute Board of Scientific Advisors.

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: National Cancer Institute Board of Scientific Advisors.

Date: November 1, 2010.

Time: 9 a.m. to 6 p.m.

Agenda: Director's Report; Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentations; Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Flr., Conf. Room 10, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, PhD, Executive Secretary, Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8001, Bethesda, MD 20892, 301-496-5147, graypp@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: <http://deainfo.nci.nih.gov/advisory/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: October 5, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26032 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Kidney Diseases in Children Ancillary Studies.

Date: November 4, 2010.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7791, goterrobinsonc@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, DDK-C Conflicts.

Date: November 16, 2010.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, ls38z@nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Gastroparesis Consortium.

Date: November 18, 2010.

Time: 2:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, davila-bloomm@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 7, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26031 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Partnerships To Advance the National Occupational Research Agenda (NORA)

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting: "Partnerships to Advance the National Occupational Research Agenda (NORA)".

Public Meeting Time and Date: 10 a.m.-3:30 p.m. EST, January 26, 2011.

Place: Patriots Plaza, 395 E Street, SW., Conference Room 9000, Washington, DC 20201.

Purpose of the Meeting: The National Occupational Research Agenda (NORA) has been structured to engage partners with each other and/or with NIOSH to advance NORA priorities. The NORA Liaison Committee continues to be an opportunity for representatives from organizations with national scope to learn about NORA progress and to suggest possible partnerships based on their organization's mission and contacts. This opportunity is now structured as a public meeting via the Internet to attract participation by a larger number of organizations and to further enhance the success of NORA. Some of the types of organizations of national scope that are especially encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome.

This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the NORA Sector Councils on their progress, priorities, and implementation plans to date, including the NORA Agriculture, Forestry, and Fishing; Healthcare and Social Assistance; Mining; Oil and Gas Extraction; and

Transportation, Warehousing, and Utilities Sector Councils. Updates will also be given on the Mid-Decade Review of NORA and the NORA Symposium 2011. After each update, there will be time to discuss partnership opportunities.

Status: The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to noracoordinator@cdc.gov containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation by Web meeting (requirements include: computer, Internet connection, and telephone, preferably with 'mute' capability) or in person. An e-mail confirming registration will include the details needed to participate in the Web meeting. Non-US citizens are encouraged to participate in the Web meeting. Non-US citizens who do not register to attend in person on or before January 7, 2011, will not be granted access to the meeting site and will not be able to attend the meeting in-person due to mandatory security clearance procedures at the Patriots Plaza facility.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see <http://www.cdc.gov/niosh/nora/about.html>.

Since 2006, NORA has been structured according to industrial sectors. Ten major sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, ten NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008–10,

most of these Councils posted draft strategic plans for public comment and eight have posted finalized National Sector Agendas after considering comments on the drafts. For the National Sector Agendas, see <http://www.cdc.gov/niosh/nora/>.

FOR FURTHER INFORMATION CONTACT: Sidney C. Soderholm, Ph.D, NORA Coordinator, E-mail noracoordinator@cdc.gov, telephone (202) 245–0665.

Dated: October 8, 2010.

Tanja Popovic,
*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*
[FR Doc. 2010–25973 Filed 10–14–10; 8:45 am]
BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin 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: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: October 25–26, 2010.

Time: 8 a.m. to 5 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: Helen Lin, PhD, Scientific Review Officer, NIH/NIAMS/RB, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301–594–4952, linh1@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 8, 2010.

Jennifer S. Spaeth,
*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2010–26068 Filed 10–14–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis (ACET)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates:

8:30 a.m.–5:30 p.m., November 2, 2010.

8:30 a.m.–2:30 p.m., November 3, 2010.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333, telephone (404) 639–8317.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: Agenda items include issues pertaining to TB outbreaks within the homeless population; TB issues along the U.S.-Mexico border; foreign born guidelines update and endorsement; Bacille Calmette-Guérin (BCG) guidelines update and endorsement; STOP TB USA retreat update; and other related tuberculosis issues. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margie Scott-Cseh, CDC, 1600 Clifton Road, NE., Mailstop E-07, Atlanta, Georgia 30333, telephone (404) 639–8317.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 6, 2010.

Elaine Baker,
*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

[FR Doc. 2010–25915 Filed 10–14–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Genetic Determinants of Healthy Aging.

Date: November 10, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elaine Lewis, PhD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC-9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7707, elainelewis@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 8, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26076 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Wound Healing Center Grant.

Date: November 9, 2010.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Meredith D. Temple-O'Connor, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301-594-2772, templeocm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26075 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, November 5, 2010, from 8:30 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT:

Jaime Zimmerman, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427-1456. For press-related information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than October 22, 2010. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality was established in accordance with Section 921 (now Section 941) of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Friday, November 5, there will be a subcommittee meeting for the National Healthcare Quality and Disparities Report scheduled to begin at 7:30 a.m. The Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The AHRQ Director will present her update on current research, programs, and initiatives. The agenda will include discussions on Operationalizing the National Quality Strategy and AHRQ's role in Operationalizing the National Health Quality Strategy. The final agenda will be available on the AHRQ

Web site at <http://www.ahrq.gov> no later than November 1, 2010.

Dated: October 5, 2010.

Carolyn M. Clancy,
Director.

[FR Doc. 2010-25774 Filed 10-14-10; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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 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 Child Health and Human Development Special Emphasis Panel; Congenital Diaphragmatic Hernia.

Date: November 9, 2010.

Time: 2 p.m. to 5 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: Neelakanta Ravindranath, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01G, Bethesda, MD 20892, 301-435-6889, ravindr@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: October 6, 2010.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26029 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; 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 Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Review of R01s.

Date: October 26, 2010.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Hungyi Shau, Scientific Review Officer, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301-402-1030, Hungyi.Shau@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: October 5, 2010.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26026 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Statistical Analysis in Support of DPMC Clinical Trials (8894).

Date: October 27-28, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301) 435-1439, lf33c.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 6, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-26024 Filed 10-14-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Delisting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of delisting.

SUMMARY: AHRQ has accepted a notification of voluntary relinquishment from the ACCE Healthcare Technology Foundation of its status as a Patient Safety Organization (PSO). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Public Law 109-41, 42 U.S.C. 299b-21-b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), 42 CFR part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory

requirements for listing. A P80 can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, including when a P80 1 chooses to voluntarily relinquish its status as a PSO for any reason.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12 Midnight ET(2400) on September 21, 2010.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>.

FOR FURTHER INFORMATION CONTACT:

Diane Cousins, RPh, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: psa@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. AHRQ has accepted a notification from the ACCE Healthcare Technology Foundation, PSO number P0017, to voluntarily relinquish its status as a PSO. Accordingly, the ACCE Healthcare Technology Foundation was delisted effective at 12:00 Midnight ET (2400) on September 21, 2010.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: October 1, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010-25771 Filed 10-14-10; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Sensitive Security Information Threat Assessments

AGENCY: Transportation Security Administration, DHS.

ACTION: 30 day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0042, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on July 30, 2010 75 FR 44974. The collection involves TSA determining whether the party or representative of a party seeking access to sensitive security information (SSI) in a civil proceeding in Federal court may be granted access to the SSI.

DATES: Send your comments by November 15, 2010. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson, TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011; telephone (571) 227-3651; e-mail TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is

available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Sensitive Security Information Threat Assessments.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652-0042.

Forms(s): TSA 2211.

Affected Public: Individuals seeking access to SSI Information.

Abstract: TSA has implemented Section 525 of the DHS Appropriations Act¹, 2007, Public Law 109-925, *see* 525(d) (October 4, 2006), as reenacted in the Department of Homeland Security Appropriations Act, 2008, Public Law 110-161, sec. 522 (Dec 26, 2007); Department of Homeland Security Appropriations, 2009, Public Law 110-329, D.V.D. sec. 510 (September 30, 2008), and Department of Homeland Security Appropriations Act 2010, Public Law 111.83, sec. 510 (October 29, 2009), by establishing a process whereby a party seeking access to SSI in a civil proceeding in federal court that demonstrates a substantial need for relevant SSI in preparation of the party's case may request that the party representative or court reporter be granted access to the SSI. In order to determine if the individual may be granted access to SSI for this purpose, TSA conducts a criminal history records check (CHRC) and threat assessment. Individuals are required to submit information including identifying information and an explanation

¹ Department of Homeland Security Appropriations Act, 2007, Pub. L. 109-925, *see* 525(d) (October 4, 2006), on reenacted in the Department of Homeland Security Appropriations Act, 2008, Public Law 110-161 Div. E. Sec. 522 (December 26, 2007); Department of Homeland Security Appropriations Act, 2009, Public Law 110-329 D.V.D. sec. 510 (September 30, 2008), and Department of Security Appropriations Act 2010, Public Law 111.83, sec. 510 (October 29, 2009).

supporting the party's need for the information.

Number of Respondents: 180.

Estimated Annual Burden Hours: An estimated 180 hours annually.

Issued in Arlington, Virginia, on October 8, 2010.

Joanna Johnson,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2010-25931 Filed 10-14-10; 8:45 am]

BILLING CODE 9110-05-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1935-DR; Docket ID FEMA-2010-0002]

Illinois; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA-1935-DR), dated August 19, 2010, and related determinations.

DATES: *Effective Date:* September 30, 2010.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 19, 2010.

Moultrie County for Public Assistance. The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-26053 Filed 10-14-10; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1930-DR; Docket ID FEMA-2010-0002]

Iowa; Amendment No. 10 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 Iowa (FEMA-1930-DR), dated July 29, 2010, and related determinations.

DATES: *Effective Date:* October 1, 2010.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 29, 2010.

Monroe County for Individual Assistance (already designated for Public Assistance). The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-26057 Filed 10-14-10; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1939-DR; Docket ID FEMA-2010-0002]

Virgin Islands; 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 Territory of the U.S. Virgin Islands (FEMA-1939-DR), dated September 28, 2010, and related determinations.

DATES: *Effective Date:* September 28, 2010.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 28, 2010, 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 Territory of the U.S. Virgin Islands resulting from Hurricane Earl during the period of August 29-31, 2010, 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 Territory of the U.S. Virgin Islands.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Territory of the U.S. Virgin Islands. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The 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, Philip E. Parr, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following islands of the Territory of the U.S. Virgin Islands have been designated as adversely affected by this major disaster:

The islands of St. Croix, St. John, and St. Thomas, including Water Island for Public Assistance.

All islands within the Territory of the U.S. Virgin Islands are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-26054 Filed 10-14-10; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5374-N-20]

Buy American Exceptions Under the American Recovery and Reinvestment Act of 2009

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: In accordance with the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-05, approved February 17, 2009) (Recovery Act), and implementing guidance of the Office of Management and Budget (OMB), this notice advises that certain exceptions to the Buy American requirement of the Recovery Act have been determined applicable for work using Capital Fund

Recovery Formula and Competition (CFRFC) grant funds. Specifically, exceptions were granted to the Cambridge Housing Authority for the purchase and installation of energy efficient bathroom exhaust fans and linoleum flooring for the Fairmont Street, Valentine Street and Jackson Street projects, and for the purchase and installation of energy efficient, hot water baseboards for its Harry S. Truman Apartments heating conversion project.

FOR FURTHER INFORMATION CONTACT:

Dominique G. Blom, Deputy Assistant Secretary for Public Housing Investments, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4130, Washington, DC, 20410-4000, telephone number 202-402-8500 (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 Information Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: Section 1605(a) of the Recovery Act provides that none of the funds appropriated or made available by the Recovery Act may be used for a project for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States. Section 1605(b) provides that the Buy American requirement shall not apply in any case or category in which the head of a Federal department or agency finds that: (1) Applying the Buy American requirement would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality, or (3) inclusion of iron, steel, and manufactured goods will increase the cost of the overall project by more than 25 percent. Section 1605(c) provides that if the head of a Federal department or agency makes a determination pursuant to section 1605(b), the head of the department or agency shall publish a detailed written justification in the **Federal Register**.

In accordance with section 1605(c) of the Recovery Act and OMB's implementing guidance published on April 23, 2009 (74 FR 18449), this notice advises the public that, on September 21, 2010, HUD granted the following two exceptions to the Buy American requirement to the Cambridge Housing Authority:

1. *Fairmont Street, Valentine Street, and Jackson Street Projects.* Upon request of the Cambridge Housing Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Fairmont Street, Valentine Street and Jackson Street projects. The exception was granted by HUD on the basis that the relevant manufactured goods (energy efficient bathroom exhaust fans and linoleum flooring) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

2. *Harry S. Truman Apartments.* Upon request of the Cambridge Housing Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Harry S. Truman Apartments heating conversion project. The exception was granted by HUD on the basis that the relevant manufactured goods (energy efficient hot water baseboards) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

Dated: October 6, 2010.

Deborah Hernandez,

General Deputy Assistant Secretary For Public and Indian Housing.

[FR Doc. 2010-26055 Filed 10-14-10; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5375-N-40]

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 possible use to assist the homeless.

DATES: *Effective Date:* October 15, 2010.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410; telephone (202) 708-1234; 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 the December 12, 1988

court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: October 7, 2010.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2010–25763 Filed 10–14–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–R–2010–N169; 80230–1265–0000–S3]

Sonny Bono Salton Sea National Wildlife Refuge Complex (Sonny Bono Salton Sea National Wildlife Refuge and Coachella Valley National Wildlife Refuge), Imperial and Riverside Counties, CA; Comprehensive Conservation Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), intend to prepare a Comprehensive Conservation Plan (CCP) and Environmental Assessment (EA) for the Sonny Bono Salton Sea National Wildlife Refuge (NWR) Complex, which consists of the Sonny Bono Salton Sea NWR located in Imperial County, California, and the Coachella Valley NWR located in Riverside County, California. We provide this notice in compliance with our CCP policy to advise other Federal and State agencies, Tribes, and the public of our intentions, and to obtain suggestions and information on the scope of issues to consider in the planning process.

DATES: To ensure consideration, we must receive your written comments by December 14, 2010.

ADDRESSES: Send your comments or requests for more information by any of the following methods.

E-mail: Victoria_Touchstone@fws.gov. Include "Sonny Bono Salton Sea CCP" in the subject line of the message.

Fax: Attn: Victoria Touchstone, (760) 930–0256.

U.S. Mail: Victoria Touchstone, U.S. Fish and Wildlife Service, Refuge Planning, 6010 Hidden Valley Road, Suite 101, Carlsbad, CA 92011.

In-Person Drop-off: You may drop off comments at the Sonny Bono Salton Sea NWR Office between 8 a.m. to 3 p.m.; please call (760) 348–5278 for directions.

FOR FURTHER INFORMATION CONTACT:

Victoria Touchstone, Refuge Planner, at 760–431–9440, extension 349, or Chris Schoneman, Project Leader, at 760–348–5278, extension 227. Further information may also be found at <http://www.fws.gov/saltonsea/>.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we initiate our process for developing a CCP for the Sonny Bono Salton Sea NWR Complex, including the Sonny Bono Salton Sea NWR in Imperial County, CA, and the Coachella Valley NWR in Riverside County, CA. This notice complies with our CCP policy to (1) advise other Federal and State agencies, Tribes, and the public of our intention to conduct detailed planning on this refuge complex, and (2) obtain suggestions and information on the scope of issues to consider in the environmental document and during development of the CCP.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We intend to review and update the CCP at least every 15 years in accordance with the Administration Act.

Each unit of the National Wildlife Refuge System was established for specific purposes. We use these purposes as the foundation for developing and prioritizing the management goals and objectives for each refuge within the National Wildlife Refuge System mission, and to determine how the public can use each refuge. The planning process is a way for us and the public to evaluate management goals, objectives, and strategies that will ensure the best possible approach to wildlife, plant, and habitat conservation, while providing for wildlife-dependent recreation opportunities that are compatible with each refuge's establishing purposes and the mission of the National Wildlife Refuge System.

Our CCP process provides opportunities for participation by Tribal, State, and local governments; agencies; organizations; and the public. We will be contacting identified stakeholders and individuals at this time for initial input. If you would like to meet with planning staff or would like to receive periodic updates, please contact us (*see ADDRESSES* section). We anticipate holding public meetings for initial comments and when alternative management scenarios have been identified. At this time we encourage comments in the form of issues, concerns, ideas, and suggestions for the future management of the Sonny Bono Salton Sea NWR and the Coachella Valley NWR.

We will conduct the environmental review of this project in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*); NEPA regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; and our policies and procedures for compliance with those laws and regulations.

Sonny Bono Salton Sea National Wildlife Refuge Complex

The Sonny Bono Salton Sea NWR Complex consists of the Sonny Bono Salton Sea NWR and the Coachella Valley NWR. The Sonny Bono Salton Sea NWR was established as a 32,766-acre sanctuary and breeding ground for birds and other wildlife in 1930 (Executive Order 5498). Additional leased lands have been added to the Refuge under the authorities of the Migratory Bird Conservation Act (16 U.S.C. 715d), "for use as an inviolate sanctuary, or for any other management propose, for migratory birds," and the Lea Act (16 U.S.C. 695), "for the management and control of migratory waterfowl, and other wildlife." Today,

with the original Refuge lands covered by the waters of the Salton Sea, management activities are focused on about 2,000 acres of primarily leased land. Approximately 920 acres consist of managed wetlands that support resident and migratory birds, and another 940 acres are farmed to provide forage for wintering geese and other migratory birds. Existing public uses include wildlife observation, photography, interpretation, environmental education, waterfowl hunting, and scientific research.

The Coachella Valley NWR was established in 1985 under the authorities of the Endangered Species Act of 1973 (16 U.S.C. 1534), "to conserve (A) fish or wildlife which are listed as endangered species or threatened species or (B) plants." The 3,709-acre Refuge, which is part of the larger Coachella Valley Preserve, protects the Federally listed endangered Coachella Valley milk-vetch (*Astragalus lentiginosus* var. *coachellae*) and threatened Coachella Valley fringe-toed lizard (*Uma inornata*), as well as other desert-dwelling species adapted to living in the sand dune habitat of the Coachella Valley. Access onto the Refuge is limited to a designated corridor for hiking and equestrian use.

Scoping: Preliminary Issues, Concerns, and Opportunities

We have identified preliminary issues, concerns, and opportunities for each Refuge that we may address in the CCP. Additional issues, concerns, and opportunities may be identified as a result of public scoping. For the Sonny Bono Salton Sea NWR, preliminary issues include: Increasing the productivity of existing managed wetlands to support migratory waterfowl; adapting to changing conditions associated with a shrinking Salton Sea (e.g., conversion of habitat types, dust management, degraded water quality); predation in seabird nesting areas; availability of adequate nesting habitat for seabirds, particularly gull-billed terns (*Gelochelidon nilotica varossemi*); and the effects of climate change on Refuge resources.

For the Coachella Valley NWR, these issues include: Habitat and species management; control of invasive weedy species; effects of windblown sand on adjacent properties; public use; and impacts to Refuge resources as a result of illegal motorized vehicle activity.

Public Meetings

We will give the public an opportunity to provide input at a public meeting (or meetings). You can obtain the schedule from the Refuge Planner or

Project Leader (*see FOR FURTHER INFORMATION CONTACT*). You may also submit comments or request a meeting during the planning process by mail, e-mail, or fax (*see ADDRESSES*). There will be additional opportunities to provide public input once we have prepared a draft CCP.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 5, 2010.

Alexandra Pitts,

Acting Regional Director, Pacific Southwest Region, Sacramento, California.

[FR Doc. 2010-25923 Filed 10-14-10; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS03100 L51010000.ER0000
LVRWF09-F8590; 10-08807; 4500013732;
TAS: 14X5017]

Notice of Availability of Final Environmental Impact Statement for the Solar Millennium, Amargosa Farm Road Solar Power Project, Nye County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Final Environmental Impact Statement (EIS) for the Amargosa Farm Road Solar Power Project, Nye County, Nevada, and by this notice is announcing its availability.

DATES: The BLM will not issue a final decision on the Amargosa Farm Road Solar Power Project for a minimum of 30 days from the date the Environmental Protection Agency publishes its notice in the **Federal Register**.

ADDRESSES: Copies of the Final EIS will be mailed to individuals, agencies, organizations, or companies who

previously requested copies or who responded to the BLM on the Draft EIS. Printed copies or a compact disc of the Final EIS are available upon request from the BLM Southern Nevada District Office, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130; phone (702) 515-5000; or e-mail at solar_millennium@blm.gov. Interested persons may also view the Final EIS at the following Web site: http://www.blm.gov/nv/st/en/prog/energy/fast-track_renewable.html. Copies of the Final EIS are available for public inspection at the following locations in Nevada:

- BLM Nevada State Office, 1340 Financial Boulevard, Reno.
- BLM Southern Nevada District Office, 4701 N. Torrey Pines Drive, Las Vegas.

FOR FURTHER INFORMATION CONTACT:

Gregory Helseth, Renewable Energy Project Manager, by phone (702) 515-5173; in writing at the Bureau of Land Management, Southern Nevada District Office, Attn: Gregory Helseth, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130; or e-mail Gregory_Helseth@blm.gov.

SUPPLEMENTARY INFORMATION: Solar Millennium applied to the BLM for a right-of-way on public lands to construct a concentrated solar thermal parabolic trough power plant facility approximately 80 miles northwest of Las Vegas, Nevada, in Nye County. The project site is located in Amargosa Valley south of Highway 95. The proposed project would encompass 4,350 acres of BLM-managed public lands, and is expected to operate for about 30 years. The proposed project would consist of two 242 megawatt dry-cooled power plants and solar fields equipped with solar thermal storage tanks capable of producing additional energy for 3.5 hours after sundown.

The solar field is highly modular and consists of "loops," each consisting of four curved glass mirror collectors. A loop is 22 meters wide by 850 meters long. A solar field consists of 200 to 400 loops. The orientation of the collectors is north-south and the collectors track the sun from east to west during the day. The collector focuses the sun's direct beam radiation on a receiver tube. The row of collectors has a hydraulic drive unit with sensors to track the sun's path throughout the day. The solar energy heats a transfer fluid which cycles through a series of exchangers, ultimately generating electricity.

The project's proposed facility design includes the solar fields, power blocks, buildings, parking area, laydown area, stormwater retention pond, and

evaporating ponds. A single overhead 230 kilovolt transmission line will connect the plant to the nearby Valley Electric substation. Additional elements of the project include access roads, a water pipeline, and a bioremediation area.

The Final EIS describes and analyzes the project's site-specific impacts on air quality, biological resources, cultural resources, visual resources, water resources, geological resources, paleontological resources, land use, noise, soils, nuisance, public health, socioeconomic, traffic and transportation, waste management, hazardous materials handling, worker safety, fire protection, facility design engineering, transmission system engineering, and transmission line safety.

Three alternatives were analyzed: (A) Wet-cooling technology; (B) Dry-cooling technology; and (C) No action alternative. Alternative A uses circulating water to condense low-pressure turbine generator exhaust steam in a shell and tube heat exchanger (condenser). Alternative B uses an air-cooled condenser that cools and condenses the low-pressure turbine generator exhaust steam using a large array of fans that force air over finned-tube heat exchangers arranged in an A-frame bundle configuration. Alternative B is the BLM's preferred alternative and Solar Millennium's proposed action. Alternative C is the no action alternative.

On March 19, 2010, the BLM published the Notice of Availability for the Draft EIS for this project in the **Federal Register** (75 FR 13301). The BLM held four public meetings and allowed the public to comment through email, mail, public meetings, and by phone. A total of 461 comments were received from individuals, organizations, and agencies.

These comments addressed concerns with water use mitigation, visual resource management, noise levels, and social/economic issues, particularly job opportunities. Concerns raised during the review are addressed and specific responses provided in the Final EIS.

Authority: 40 CFR 1506.6 and 1506.10.

Gayle Marrs-Smith,

Acting Manager Pahrump Field Office.

[FR Doc. 2010-25859 Filed 10-14-10; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

Outer Continental Shelf, Alaska OCS Region, Chukchi Sea Planning Area, Oil and Gas Lease Sale 193

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Notice of Availability of a Draft Supplemental Environmental Impact Statement (SEIS) and Notice of Public Hearings.

SUMMARY: The purpose of this SEIS (OCS EIS/EA BOEMRE 2010-034) is to provide new analysis in accordance with the United States (U.S.) District Court for the District of Alaska Order remanding the BOEMRE's Chukchi Sea Lease Sale 193 Final EIS (FEIS) (OCS EIS/EA MMS 2007-0026). The District Court's Order instructs the BOEMRE to address three concerns: (1) Analyze the environmental impact of natural gas development; (2) determine whether missing information identified by BOEMRE in the 193 FEIS was essential or relevant under 40 CFR 1502.22; and (3) "determine whether the cost of obtaining the missing information was exorbitant, or the means of doing so unknown."

SUPPLEMENTARY INFORMATION: The FEIS for Chukchi Sea Lease Sale 193 (OCS EIS/EA MMS 2007-0026) evaluated the potential effects of the proposed sale and three alternatives: a no action alternative and two alternatives that incorporate deferral areas of varying size along the coastward edge of the proposed sale area.

Sale 193 was held in February of 2008. The BOEMRE received high bids totaling approximately \$2.7 billion and issued 487 leases. Although the lease-sale decision was challenged in the U.S. District Court for the District of Alaska, the litigants did not request a preliminary injunction to halt the sale. Accordingly, the sale was conducted and 487 leases were issued. In July 2010, the District Court remanded the matter for further National Environmental Policy Act analysis of certain concerns. The BOEMRE is to address three concerns: (1) Analyze the environmental impact of natural gas development; (2) determine whether missing information identified by BOEMRE in the FEIS for Chukchi Sea Lease Sale 193 was essential or relevant under 40 CFR 1502.22; and (3) determine whether the cost of obtaining the missing information was exorbitant, or the means of doing so unknown.

The SEIS will provide the Secretary with sufficient information and analysis to make an informed decision amongst the alternatives. In effect, the Secretary will decide whether to affirm, modify, or cancel Sale 193. This notice relates solely to the Supplemental Draft EIS for Chukchi Sale 193. It does not preclude possible additional environmental analysis with regard to future leasing or permitting actions.

Draft Supplemental EIS Availability: To obtain a copy of the Draft SEIS, you may contact the Bureau of Ocean Energy Management, Regulation and Enforcement, Alaska OCS Region, 3801 Centerpoint Drive, Suite 500, Anchorage, Alaska 99503-5820, telephone 907-334-5200. You may also view the Draft SEIS at the above address, on the BOEMRE Web site at <http://alaska.boemre.gov>, or at the Alaska Resources Library and Information Service, 3211 Providence Drive, Suite 111, Anchorage.

Written Comments: Interested parties may submit their written comments on the Draft SEIS until November 29, 2010 to the Regional Director, Alaska OCS Region, Bureau of Ocean Energy Management, Regulation and Enforcement, 3801 Centerpoint Drive, Suite 500, Anchorage, Alaska 99503-5820. You may also hand deliver comments to this address. Comments should be labeled "Attn: Chukchi Sea Draft SEIS." Comments may be submitted via e-mail at BOEMREAKPublicCommen@boemre.gov (**Note:** please use e-mail address exactly as it appears. Do not add the letter "q" or anything else to the address.). Please include "Attn: Chukchi Sea Draft SEIS" in the subject line, and your name and return address in the message. BOEMRE will not accept anonymous comments.

Be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request us to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Public Hearings: Public hearings on the Draft SEIS will be held as follows:

Monday, November 1, 2011, Kotzebue Middle/High School, Kotzebue, Alaska;

Tuesday, November 2, 2010, Oalgi Community Center, Point Hope, Alaska;

Wednesday, November 3, 2010, Point Lay Community Center, Point Lay, Alaska;

Thursday, November 4, 2010, Robert James Community Center, Wainwright, Alaska;

Friday, November 5, 2010, Inupiat Heritage Center, Barrow, Alaska;

Tuesday, November 9, 2010, 3800
Centerpoint Drive, Anchorage, Alaska.
All meetings will start at 7 p.m.

FOR FURTHER INFORMATION CONTACT:
Bureau of Ocean Energy Management,
Regulation and Enforcement, Alaska
OCS Region, 3801 Centerpoint Drive,
Suite 500, Anchorage, Alaska 99503–
5820, 907–334–5200.

Dated: October 8, 2010.

Robert P. LaBelle,

*Acting Associate Director for Offshore Energy
and Minerals Management.*

[FR Doc. 2010–25938 Filed 10–14–10; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–R–2010–N170; 30136–1265–0000–
S3]

Crane Meadows National Wildlife Refuge, Morrison County, MN

AGENCY: U.S. Fish and Wildlife Service,
Department of the Interior.

ACTION: Notice of availability: Final
Comprehensive Conservation Plan and
Finding of No Significant Impact for
Environmental Assessment.

SUMMARY: We, the U.S. Fish and
Wildlife Service (Service), announce the
availability of the Final Comprehensive
Conservation Plan (CCP) and Finding of
No Significant Impact (FONSI) for the
Environmental Assessment (EA) for
Crane Meadows National Wildlife
Refuge (NWR). Goals and objectives in
the CCP describe how the agency
intends to manage the refuge over the
next 15 years.

ADDRESSES: Copies of the Final CCP and
FONSI/EA may be viewed at the Crane
Meadows National Wildlife Refuge
Office or at public libraries near the
refuge. You may also request a copy by
any of the following methods.

1. *Agency Web site:* View or
download a copy of the document at
[http://www.fws.gov/midwest/planning/
CraneMeadows/](http://www.fws.gov/midwest/planning/CraneMeadows/).

2. *E-mail:* r3planning@fws.gov.
Include “Crane Meadows Final CCP/EA”
in the subject line of the message.

3. *Mail:* Crane Meadows National
Wildlife Refuge, 19502 Iris Road, Little
Falls, Minnesota 56345.

A limited number of hardcopies will
be available for distribution at the
Refuge Headquarters.

FOR FURTHER INFORMATION CONTACT:
Anne Sittauer (763–389–3323).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we complete the
CCP process for Crane Meadows NWR,
which we began by publishing a notice
of intent on (73 FR 76677–76678,
December 17, 2008). For more
information about the initial process,
see that notice. We released the draft
CCP and EA to the public, announcing
and requesting comments in a notice of
availability on (75 FR 39037–39038, July
7, 2010).

Crane Meadows NWR, located in
central Minnesota, was established in
1992 to protect one of the largest, most
intact wetland complexes remaining in
the State. The Refuge owns
approximately 1,800 acres of 13,540
acres identified for acquisition, and an
additional 900 acres are owned and
managed by the Minnesota Department
of Natural Resources. In addition to
hosting relatively rare habitat types
including oak savanna, sand prairie, and
sedge meadow, it also provides key
habitat for local and migratory wildlife,
maintains essential ecological services,
provides an element of water control
and flood relief, protects important
archaeological resources, and offers
unique recreation, education, and
research opportunities.

The Draft CCP and EA were officially
released for public review on July 7,
2010; the 31-day comment period ended
on August 6, 2010. Planning
information was sent to approximately
265 individuals and organizations for
review and announced through local
media outlets, resulting in three
comment submissions. During the
comment period the Refuge also hosted
an open house to receive public
comments and feedback on the CCP and
EA documents. Three individuals
attended this event—all current or
former state Department of Natural
Resources employees. Because no
changes to the preferred alternative
were recommended by Refuge
audiences during the public review
period, only minor changes were made
to the drafts in preparing the final CCP/
EA documents.

Selected Alternative

Based on input and feedback during
the planning process, alternative B was
selected as the preferred alternative.
This alternative portrays a long-term
vision for habitat restoration to near-
historic benchmark conditions and
increases recreation opportunities for
visitors over the 15-year planning
horizon. A diversity of wetland and
savanna habitats are favored reinforcing
historic conditions, while prairie and
woodland are reduced over the long-

term. This alternative includes active
participation in monitoring and
improving upstream water resources,
calls for adherence to a well-developed
prescribed fire plan, increases land
acquisition and work on private lands in
high priority areas, augments the
existing biological inventory and
monitoring program, and offers visitor
services in a greater number of
locations. Specific, managed hunts are
offered, and opportunities for quality
fishing experiences will be evaluated as
new lands are acquired.

Background

The National Wildlife Refuge System
Administration Act of 1966, as amended
by the National Wildlife Refuge System
Improvement Act of 1997 (16 U.S.C.
668dd–668ee *et seq.*), requires the
Service to develop a CCP for each
National Wildlife Refuge. The purpose
in developing a CCP is to provide refuge
managers with a 15-year strategy for
achieving refuge purposes and
contributing toward the mission of the
National Wildlife Refuge System,
consistent with sound principles of fish
and wildlife management, conservation,
legal mandates, and Service policies. In
addition to outlining broad management
direction for conserving wildlife and
their habitats, the CCP identifies
wildlife-dependent recreational
opportunities available to the public,
including opportunities for hunting,
fishing, wildlife observation and
photography, and environmental
education and interpretation.

We will review and update the CCP
at least every 15 years in accordance
with the National Wildlife Refuge
System Administration Act of 1966, as
amended by the National Wildlife
Refuge System Improvement Act of
1997, and the National Environmental
Policy Act of 1969 (42 U.S.C. 4321–
4370d).

Dated: August 17, 2010.

Charles M. Wooley,

*Acting Regional Director, U.S. Fish and
Wildlife Service, Ft. Snelling, Minnesota.*

[FR Doc. 2010–25971 Filed 10–14–10; 8:45 am]

BILLING CODE 4310–55–P

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

Renewal of Advisory Committee on Actuarial Examinations

AGENCY: Joint Board for the Enrollment
of Actuaries.

ACTION: Renewal of Advisory
Committee.

SUMMARY: The Joint Board for the Enrollment of Actuaries announces the renewal of the Advisory Committee on Actuarial Examinations.

FOR FURTHER INFORMATION CONTACT: Patrick W. McDonough, 202-622-8225.

SUPPLEMENTARY INFORMATION: The purpose of the Committee is to advise the Joint Board on examinations in actuarial mathematics and methodology. The Joint Board administers such examinations in discharging its statutory mandate to enroll individuals who wish to perform actuarial services with respect to pension plans subject to the Employee Retirement Income Security Act of 1974. The Committee's advisory functions will include, but will not necessarily be limited to: (1) Considering areas of actuarial knowledge that should be treated on the examinations; (2) developing examination questions; (3) recommending proposed examinations and pass marks; and (4), as requested by the Joint Board, making recommendations relative to the examination program.

Dated: October 7, 2010.

Patrick W. McDonough,

Executive Director, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2010-25951 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act; the Clean Water Act; the Resource Conservation and Recovery Act; the Emergency Planning and Community Right-To-Know Act; and the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on October 8, 2010, a proposed Consent Decree in *United States and State of Missouri v. The Doe Run Resources Corporation, et al.*, Civil Action 4:10-cv-1895 was lodged with the United States District Court for the Eastern District of Missouri.

In this action the United States and the State of Missouri sought civil penalties and injunctive relief for environmental violations of the Clean Air Act, 42 U.S.C. 7401-7671q; the Missouri Air Conservation Law, Chapter 643, RSMo; the Resource Conservation and Recovery Act, 42 U.S.C. 6901-6992k; the Missouri Hazardous Waste Management Law, §§ 260.350-260.434, RSMo; the Clean Water Act, 33 U.S.C. 1251-1387; the Missouri Clean Water Law, Chapter 644, RSMo; the

Emergency Planning and Community Right-to-Know Act, 42 U.S.C. 11001-11050; and the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601-9603 at several of the mining, milling, and smelting facilities located in Missouri owned and operated by The Doe Run Resources Corporation, The Doe Run Resources Corporation d/b/a "The Doe Run Company", and The Buick Resource Recycling Facility, LLC ("Defendants"). To resolve the United States' and State's claims the Defendants will pay a civil penalty of \$7 million. The penalty will be paid in a \$3.5 million payment to the United States and a \$1.5 million payment to the state of Missouri, with an additional \$1 million plus interest to be paid to the state each year for the next two years. The settlement also requires Doe Run to establish financial assurance trust funds for the cleanup of the following active or former mining and milling facilities: Brushy Creek, Buick, Fletcher, Sweetwater, Viburnum, and West Fork. Doe Run will also take steps to address RCRA violations at certain facilities; finalize and come into compliance with more stringent Clean Water Act permits at 10 of its facilities, including Herculaneum, Glover, Brushy Creek, Buick Mill, Fletcher, Sweetwater, Viburnum, West Fork, Mine #35 (Casteel), and Buick Resource Recycling; and will spend an estimated \$5.8 million on stream mitigation activities along 8.5 miles of Bee Fork Creek, an impaired waterway near Doe Run's Fletcher mine and mill facility. At four facilities, Buick Mine, Brushy Creek, Fletcher, and Sweetwater, Doe Run will also enclose the lead concentrate handling, loading, and storage areas under negative pressure with emissions routed to a baghouse. The company will also spend \$2 million on community mitigation projects over the next four years.

In addition, instead of installing pollution control technologies needed to reduce sulfur dioxide and lead emissions as required by the Clean Air Act, Doe Run has made a business decision to shut down its lead smelter in Herculaneum, Mo., by Dec. 31, 2013. The company will also provide an initial \$8.14 million in financial assurance to guarantee cleanup work at the Herculaneum facility.

The Department of Justice will receive for a period of 30 days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to pubcomment-ees.enrd@usdoj.gov or

mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States, et al. v. The Doe Run Resources Corporation, et al.*, D.J. Ref. 90-5-2-1-07390/1. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of the Resource Conservation and Recovery Act, 42 U.S.C. 6973.

The Consent Decree may be examined at the Office of the United States Attorney, Eastern District of Missouri, Thomas F. Eagleton U.S. Courthouse, 111 South 10th Street, Room 20.333, St. Louis, MO 63102 Tel.: (314) 539-2200 and at EPA Region 7, 901 N. 5th Street, Kansas City, KS 66101, Tel: 1-800-223-0425.

During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site, http://www.usdoj.gov/enrd/Consent_Decrees.html. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check to cover the 25 cents per page reproduction costs in the amount of \$43.50 (for Decree without appendices) or \$113.25 (for Decree with appendices) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010-25930 Filed 10-14-10; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2010-0041]

Logging Operations; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified in its Standard on Logging Operations (29 CFR 1910.266).

DATES: Comments must be submitted (postmarked, sent, or received) by December 14, 2010.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA-2010-0041, U.S. Department of Labor, Occupational Safety and Health Administration, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number for the information collection requirements (ICR) (OSHA-2010-0041). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at <http://www.regulations.gov>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Paragraph (f)(1)(iii) of the Standard requires the employer to assure that operating and maintenance instructions are available on machines or in the area where the machine is being operated. Paragraph (g)(3) requires the employer to assure that operating and maintenance instructions are available in each vehicle.

Paragraph (i)(1) of the Standard requires employers to provide training for each employee, including supervisors. To meet this requirement, employers must conduct the training at the frequencies specified by paragraph (i)(2). Paragraph (i)(3) specifies that a worker's/supervisor's training must consist of the following elements: Safe work practices, including the use, operation, and maintenance of tools, machines, and vehicles the worker/supervisor uses or operates, as well as procedures, practices, and requirements of the employer's worksite; recognition and control of health and safety hazards associated with the worker's/supervisor's specific work tasks and

logging operations in general; and the requirements of the Standard.

Paragraph (i)(10)(i) specifies that employers must verify that they are in compliance with the training requirements in paragraph (i). This certification must be in writing and provide the following information: The name/identifier of the worker/supervisor; the date(s) of the training; and either the signature of the employer or the individual who conducted the training. Paragraph (i)(10)(ii) requires employers to maintain the most recent certification for training completed by an employee/supervisor.

Training workers/supervisors in safe work practices and to recognize and control the safety and health hazards associated with their work tasks and overall logging operations enables them to prevent serious accidents by using specific procedures and equipment in a safe manner to avoid or to control dangerous exposures to these hazards.

Establishing and maintaining written certification of the training that each worker/supervisor has received (*i.e.*, job and first aid) assures the employer that the training specified by the Standard has been conducted, and at the required frequencies. With regard to first-aid training, the certification assures that the worker's/supervisor's training certificate is currently valid. In addition, these records provide the most efficient means for an OSHA compliance officer to determine whether an employer performed the required training at the necessary and appropriate frequencies.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Standard on Logging Operations (29 CFR 1910.266). The Agency is requesting to decrease its existing

burden hours from 31,286 hours to 25,957 for a total decrease of 5,329 hours. This decrease is the result of updated data which shows a decrease in the number of logging establishments. The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Logging Operations (29 CFR 1910.266).

OMB Number: 1218-0198.

Affected Public: Business or other for-profits.

Number of Respondents: 10,038.

Frequency of Recordkeeping: Initially, on occasion.

Average Time per Response: Varies from 1 minute (.02 hour) to maintain training certification records to 3 hours to conduct initial training.

Estimated Total Burden Hours: 25,957.

Estimated Cost (Operation and Maintenance): \$0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows:

(1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA-2010-0041). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled ADDRESSES). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627.

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social

security numbers and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 4-2010 (75 FR 55355).

Signed in Washington, DC, on October 12, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2010-25978 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-74,548]

Propex Operating Company, LLC, Including On-Site Leased Workers From Ambassador Personnel, the Pollard Agency and PFMI, Bainbridge, Georgia; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 10, 2010, applicable to workers of Propex Operating Company, LLC, including on-site leased workers from Ambassador Personnel, Bainbridge, Georgia. The notice was published in the **Federal Register** on September 23, 2010 (75 FR 57982).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers are engaged in

activities related to the production of spun yarn.

The company reports that workers leased from The Pollard Agency and PFMI were employed on-site at the Bainbridge, Georgia location of Propex Operating Company, LLC. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from The Pollard Agency and PFMI working on-site at the Bainbridge, Georgia location of Propex Operating Company, LLC.

The amended notice applicable to TA-W-74,548 is hereby issued as follows:

All workers of Propex Operating Company, LLC, including on-site leased workers from Ambassador Personnel, The Pollard Agency and PFMI, Bainbridge, Georgia, who became totally or partially separated from employment on or after August 18, 2009, through September 10, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 1st day of October 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010-26018 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-74,489]

Warner Chilcott Pharmaceuticals, Inc. Including On-Site Leased Workers From Adecco Engineering and Technical, Norwich, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 10, 2010, applicable to workers of Warner Chilcott Pharmaceuticals, Inc., Norwich, New York. The notice was published in the **Federal Register** on September 23, 2010 (75 FR 57982).

At the request of a petitioner, the Department reviewed the certification

for workers of the subject firm. The workers were engaged in employment related to the supply of pharmaceutical research and development services.

The company reports that workers leased from Adecco Engineering and Technical were employed on-site at the Norwich, New York location of Warner Chilcott Pharmaceuticals, Inc. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Adecco Engineering and Technical working on-site at the Norwich, New York location of Warner Chilcott Pharmaceuticals, Inc.

The amended notice applicable to TA-W-74,489 is hereby issued as follows:

All workers of Warner Chilcott Pharmaceuticals, Inc., including on-site leased workers from Adecco Engineering and Technical, Norwich, New York, who became totally or partially separated from employment on or after August 6, 2009, through September 10, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 8th day of October 2010.

Elliott S. Kushner,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010-26017 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-72,933]

Hewlett Packard, Hewlett Packard—Enterprise Business Services, Formerly Known as Electronic Data Systems, Including On-Site Leased Workers From Sun Microsystems, Inc., Dell Computer Corp., EMC Corp., EMC Corp. Total, Cisco Systems Capital Corporation, Microsoft Corp., Symantec Corp., Xerox Corp., VMWare, Inc., Sun Microsystems Federal, Inc., ABM Business Machines, Inc., and Vision IT Pontiac, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”),

19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 25, 2010, applicable to workers of Hewlett Packard, Hewlett Packard—Enterprise Business Services, formerly known as Electronic Data Systems, including on-site leased workers from the above listed firms, Pontiac, Michigan. The Department’s Notice of determination was published in the **Federal Register** on March 5, 2010 (75 FR 10322). The notice was amended on July 13, 2010 to correct the impact date. The notice was published in the **Federal Register** on July 26, 2010 (75 43555).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to information technology services.

New information shows that workers leased from Vision IT were employed on-site at the Pontiac, Michigan location of Hewlett Packard, Hewlett Packard—Enterprise Business Services, formerly known as Electronic Data Systems. The Department has determined that these workers were sufficiently under the control of Hewlett Packard, Hewlett Packard—Enterprise Business Services, formerly known as Electronic Data Systems to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Vision IT working on-site at the Pontiac, Michigan location of Hewlett Packard, Hewlett Packard—Enterprise Business Services, formerly known as Electronic Data Systems.

The intent of the Department’s certification is to include all workers employed Hewlett Packard, Hewlett Packard—Enterprise Business Services, formerly known as Electronic Data Systems who were adversely affected by the acquisition of information technology services to India.

Accordingly, the Department is amending this certification to properly reflect this matter.

The amended notice applicable to TA-W-72,933 is hereby issued as follows:

All workers of Hewlett Packard, Hewlett Packard—Enterprise—Services, formerly known as Electronic Data Systems, including on-site leased workers from Sun Microsystems, Inc., Dell Computers Corp., EMC Corp., EMC Corp. Total, Cisco Systems Capital Corp., Microsoft Corp., Symantec Corp., Xerox Corp., VMWare, Inc., Sun Microsystems Federal, Inc., ABM Business Machines, Inc., Vision IT, Pontiac, Michigan, who became totally or partially separated from employment on or after June 25, 2008,

through January 25, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through January 25, 2012, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of October 2010.

Elliott S. Kushner,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010-26016 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA-W) number issued during the period of September 27, 2010 through October 1, 2010.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers’ firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a

domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|----------------------|-----------------|
| 73,874 | The Wise Company, Inc. (B&M Seating) | Memphis, TN | April 6, 2009. |
| 73,877 | L.A. Najarian, Inc | Greene, NY | March 29, 2009. |
| 74,020 | The Electric Materials Company, Subsidiary of United Stars | North East, PA | April 12, 2009. |
| 74,349 | Belding Hausman, Inc., Weldon Mill, Leased Workers from Compensation Management. | Emporia, VA | June 28, 2009. |

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|----------------------|----------------|
| 73,621 | Thermo Fisher Hamilton, Subsidiary of Thermo Fisher Scientific, Lab Works Stations Division. | Two Rivers, WI | March 2, 2009. |

| TA-W No. | Subject firm | Location | Impact date |
|----------|--|----------------------|---------------------|
| 74,272 | Medtronic, Inc., Cardiac Rhythm Disease Management, Leased Workers of Advantage Technical, etc. | Mounds View, MN | June 21, 2009. |
| 74,337 | Certegy Check Services, Inc., Fidelity National Payment Services, Leased Workers from Appleone. | West Valley City, UT | June 30, 2009. |
| 74,385 | Mermec, Inc., FKA ImageMap, Inc., Leased Worker from Modis, Inc. | Columbia, SC | July 13, 2009. |
| 74,464 | BreconRidge Manufacturing Solutions, Sanmina-SCI Corporation, Leased Workers from Kelly Services and Penski. | Ogdensburg, NY | July 29, 2009. |
| 74,467 | Zach System Corporation, Zach System SPA, Leased Workers of Turner Industries and Go. | La Porte, TX | August 3, 2009. |
| 74,491 | Acme Electric, Actuant Corporation, Leased Workers From Mega Force Staffing. | Lumberton, NC | August 15, 2010. |
| 74,504 | American Girl Brands, LLC, Subsidiary of Mattel, Inc | Middleton, WI | August 6, 2009. |
| 74,517 | Hotels.Com, An Expedia, Inc. Company, Latam | Arlington, TX | July 31, 2009. |
| 74,556 | Telair International, Incorporated, Nordisk Aviation Products Division. | Simi Valley, CA | July 20, 2009. |
| 74,567 | Janssen R&D and Janssen Pharmaceutical Supply Group, Divisions of J&J. | Springhouse, PA | August 24, 2009. |
| 74,580 | Fiskars Brands, Inc., Garden Division, On-Site Leased Workers of QTI. | Sauk City, WI | August 31, 2009. |
| 74,580A | Fiskars Brands, Inc., School, Office and Craft Division, On-Site Leased Workers of Manpower. | Wausau, WI | August 31, 2009. |
| 74,585 | Georgia-Pacific Wood Products LLC | Grenada, MS | August 26, 2009. |
| 74,606 | Watson Laboratories, Inc., Watson Pharmaceuticals, Danbury Pharmacal, Leased Workers Adecco Staffing. | Carmel, NY | September 3, 2009. |
| 74,621 | Burgess-Norton Manufacturing Company, Inc., Leased Workers from Selectremedy and Manpower. | Claremore, OK | September 10, 2009. |
| 74,657 | STMicroelectronics, Inc | Phoenix, AZ | October 31, 2010. |

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|----------|---|------------------|--------------------|
| 72,947 | Supreme Foam, Inc | Archdale, NC | November 17, 2008. |
| 74,425 | Douglas Corporation, Leased Workers Masterson Personnel, Just in Case, etc. | Eden Prairie, MN | July 22, 2009. |
| 74,471 | Alumax Service Center, Division of SAPA Extrusions, Leased Workers of Manpower Temporary. | Riverside, MO | July 15, 2009. |
| 74,592 | Interstate Electronics Corp., L-3 Communications, Leased Workers of Bently Global Resources, etc. | Anaheim, CA | August 31, 2009. |
| 74,600 | Lear Corporation | Louisville, KY | September 3, 2009. |

The following certifications have been issued. The requirements of Section 222(c) (downstream producer for a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|----------|--------------------------|------------|-----------------|
| 74,569 | Titus Transportation, LP | Denton, TX | August 24, 2009 |

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility

criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or

(b)(1), or (c)(1)(employment decline or threat of separation) of section 222 has not been met.

| TA-W No. | Subject firm | Location | Impact date |
|----------|---|---------------------|-------------|
| 73,846 | AT&T Operations, Inc., Network Management Center | Boulder, CO. | |
| 74,191 | Pennsylvania Railcar—Plant #2, dba Railcar Services Company | West Middlesex, PA. | |
| 74,506 | Axiom CDC Corporation | Chicago, IL. | |

The investigation revealed that the criteria under paragraphs (a)(2)(A)(i)

(decline in sales or production, or both) and (a)(2)(B) (shift in production or

services to a foreign country) of section 222 have not been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|-----------------|-------------|
| 74,564 | Ally Financial Incorporated, Motor Acceptance Corp. (GMAC), Auctioneering Unit, Darlington Auto Auction. | Darlington, SC. | |

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|---|-----------------|-------------|
| 72,765 | Mount Vernon Consulting, LLC, Workers' Wages Were Reported Under 14 W. Administrative Services, Agora, Inc. | Baltimore, MD. | |
| 73,395 | Roddie Trucking, LLC, SWR, Inc. | San Angelo, TX. | |
| 73,972 | Saint Barnabas Health Care System, Patient Accounting Dept., Leased Workers, Liberty and Tritech. | Ocean Port, NJ. | |
| 74,040 | Cemex Construction Materials Atlantic, LLC, Wampum Cement Plant. | Wampum, PA. | |
| 74,136 | Parker Paint Company | Beaverton, OR. | |
| 74,320 | United Steelworkers Local 746L | Tyler, TX. | |
| 74,528 | United Auto Workers Local 2166, UAW | Shreveport, LA. | |

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and

on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|-----------------|-------------|
| 74,248 | EDS, an HP Company (Re-Branded as HP—Enterprise Services), Virtual Workers Across the United States. | Palo Alto, CA. | |
| 74,343 | JohnsonDiversey | Santa Cruz, CA. | |

The following determinations terminating investigations were issued because the petitioning groups of

workers are covered by active certifications. Consequently, further investigation in these cases would serve

no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|---|-----------------|-------------|
| 74,603 | Thermo EGS Gauging, Inc., Field Service Engineers | Wilmington, MA. | |

I hereby certify that the aforementioned determinations were issued during the period of September 27, 2010 through October 1, 2010. Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or tofoiarequest@dol.gov. These determinations also are available on the Department's Web site at <http://www.doleta.gov/tradeact> under the searchable listing of determinations.

Dated: October 8, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010-26014 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the

determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than October 25, 2010.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than October 25, 2010.

Copies of these petitions may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail, to FOIA Disclosure Officer, Office

of Trade Adjustment Assistance (ETA),
U.S. Department of Labor, 200
Constitution Avenue, NW., Washington,
DC 20210 or to foiarequest@dol.gov.

Signed at Washington, DC, this 7th day of
October 2010.

Elliott S. Kushner,
*Certifying Officer, Division of Trade
Adjustment Assistance.*

APPENDIX

[TAA petitions instituted between 9/27/10 and 10/1/10]

| TA-W | Subject firm (petitioners) | Location | Date of institution | Date of petition |
|-------|--|----------------------|---------------------|------------------|
| 74666 | Goodyear (State/One-Stop) | Portland, OR | 09/27/10 | 09/25/10 |
| 74667 | International Business Machines Corporation (IBM) (Company). | Boulder, CO | 09/27/10 | 09/24/10 |
| 74668 | Communication Cable Company (Workers) | Malvern, PA | 09/27/10 | 09/24/10 |
| 74669 | Greif Brothers Corporation (Union) | Washington, PA | 09/27/10 | 09/24/10 |
| 74670 | McCrorie Wood Products (Company) | Hickory, NC | 09/29/10 | 09/28/10 |
| 74671 | Global Parts Supply Chain (State/One-Stop) | Houston, TX | 09/29/10 | 09/23/10 |
| 74672 | Dell Perot Systems (State/One-Stop) | Lincoln, NE | 09/29/10 | 09/07/10 |
| 74673 | The San Bernardino Sun (Workers) | San Bernardino, CA | 09/29/10 | 09/22/10 |
| 74674 | AR Knitwear Company, Inc. (Workers) | North Bergen, NJ | 09/29/10 | 09/20/10 |
| 74675 | IBM, Incorporated (State/One-Stop) | Simsbury, CT | 09/29/10 | 07/30/10 |
| 74676 | Sparton Medical Systems Corporation (State/One-Stop) | Frederick, CO | 09/29/10 | 09/28/10 |
| 74677 | Hospira, Incorporated (Company) | Pleasant Prairie, WI | 09/29/10 | 08/30/10 |
| 74678 | Primus International, Inc. (State/One-Stop) | Algona, WA | 09/29/10 | 09/27/10 |
| 74679 | LSI Greenlee Lighting, Inc. (Company) | Carrollton, TX | 09/29/10 | 09/17/10 |
| 74680 | Stanley Black and Decker (Company) | East Greenwich, RI | 09/29/10 | 09/08/10 |
| 74681 | Tower-OHL Group (Workers) | Jacksonville, FL | 09/29/10 | 09/27/10 |
| 74682 | Broadview Network Holdings, Inc. (Workers) | Rye Brook, NY | 09/29/10 | 09/27/10 |
| 74683 | Los Angeles Newspaper Group (Workers) | San Bernardino, CA | 09/29/10 | 09/23/10 |
| 74684 | Quad-Graphics (Workers) | Clarksville, TN | 09/29/10 | 09/28/10 |
| 74685 | Coats American, Inc. (Company) | Charlotte, NC | 10/01/10 | 09/28/10 |
| 74686 | Diebold Software, Inc. (Workers) | Raleigh, NC | 10/01/10 | 09/24/10 |
| 74687 | Burns Industrial Group (Company) | Hinckley, OH | 10/01/10 | 09/29/10 |
| 74688 | PricewaterhouseCoopers (Workers) | Tampa, FL | 10/01/10 | 09/30/10 |
| 74689 | Amdocs, Inc. (State/One-Stop) | New Haven, CT | 10/01/10 | 09/29/10 |
| 74690 | Mount Vernon Mills, Inc. (Company) | Mauldin, SC | 10/01/10 | 09/29/10 |

[FR Doc. 2010-26013 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-71,291]

Modine Manufacturing Company Including On-Site Leased Workers From Securitas, Aerotek and Accountemps, Pemberville, Ohio; Amended Notice of Revised Determination on Reconsideration

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Notice of Revised Determination on Reconsideration on July 30, 2010. The Notice of revised determination was published in the **Federal Register** on August 13, 2010 (75 FR 49538).

At the request of the State agency, the Department reviewed the revised determination applicable to workers and former workers of Modine Manufacturing Company, Pemberville,

Ohio (subject firm). The workers are engaged in employment related to the production of radiators and service parts.

The company reports that workers leased from Securitas, Aerotek, and Accountemps were employed on-site at the Pemberville, Ohio location of Modine Manufacturing Company. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Securitas, Aerotek, and Accountemps working on-site at the Pemberville, Ohio location of Modine Manufacturing Company.

The amended notice applicable to TA-W-71,291 is hereby issued as follows:

All workers of Modine Manufacturing Company, including on-site leased workers from Securitas, Aerotek, and Accountemps, Pemberville, Ohio, who became totally or partially separated from employment on or after June 12, 2008, through July 30, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years

from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 6th day of October 2010.

Del Min Amy Chen,
Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2010-26015 Filed 10-14-10; 8:45 am]

BILLING CODE 4510-FN-P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

Sunshine Act Meetings

TIME AND DATE: 9 a.m. to 12 p.m., Friday, October 29, 2010.

PLACE: The offices of the Morris K. Udall and Stewart L. Udall Foundation, 130 South Scott Avenue, Tucson, AZ 85701.

STATUS: This meeting will be open to the public, unless it is necessary for the Board to consider items in executive session.

MATTERS TO BE CONSIDERED: (1) A report on the U.S. Institute for Environmental Conflict Resolution; (2) A report from

the Udall Center for Studies in Public Policy; (3) A report on the Native Nations Institute; (4) Program Reports; and (5) A Report from the Management Committee.

PORTIONS OPEN TO THE PUBLIC: All sessions with the exception of the session listed below.

PORTIONS CLOSED TO THE PUBLIC: Executive session.

CONTACT PERSON FOR MORE INFORMATION: Ellen K. Wheeler, Executive Director, 130 South Scott Avenue, Tucson, AZ 85701, (520) 901-8500.

Dated: October 6, 2010.

Ellen K. Wheeler,

Executive Director, Morris K. Udall and Stewart L. Udall Foundation, and Federal Register Liaison Officer.

[FR Doc. 2010-25779 Filed 10-14-10; 8:45 am]

BILLING CODE 6820-FN-M

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35) (PRA). The original submission was made in connection with proposed amendments to the agency's rule governing corporate credit unions (12 CFR part 704), as approved by the NCUA Board in November, 2009 and published in the **Federal Register** on December 9, 2009 (74 FR 65210). In view of changes made in the final rule that affect (by reducing) the original burden estimates, as described below, OMB has requested that the agency provide another opportunity for public comment.

DATES: Comments will be accepted until November 15, 2010.

ADDRESSES: Interested parties are invited to submit written comments to the National Credit Union Administration, Office of the Chief Information Officer as listed below: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428, Fax No. 703-837-2861, *E-mail:* OCIOmail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or a

copy of the information collection request should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428, or at (703) 518-6444. Copies of the final rule, as approved by the NCUA Board at its September 24 Board meeting, are available on the agency's Web site, <http://www.NCUA.gov>.

SUPPLEMENTARY INFORMATION: Proposal for the following collection of information:

OMB Number: 3133-0129.

Form Number: None.

Type of Review: Revision of a previously approved collection.

Title: Corporate Credit Unions.

Description: Part 704 of NCUA's Rules and Regulations imposes certain information collection obligations on corporate credit unions concerning their activities. As described in the preamble to the proposed rule, information collection requirements, within the meaning of the PRA, are included in the following aspects of the rule: With respect to capital and prompt corrective action requirements, the new rule creates several new capital standards and requirements, which have the potential to increase the likelihood of having to prepare a capital restoration plan, or modify an existing plan. Beginning three years after the effective date of the rule, some corporates may be required to develop and submit a retained earnings accumulation plan. The rule generally requires a corporate to obtain NCUA's prior approval before permitting the early redemption of contributed capital, and the rule imposes notice requirements in the event changes occur that cause the corporate to be placed in a lower capital category, within the prompt corrective action realm. The rule also imposes new requirements concerning the use of nationally recognized statistical rating agencies, which may have the effect of triggering new or modified investment action plans. In terms of asset-liability management, two cash flow mismatch tests that had been proposed have been eliminated from the final rule, but testing for weighted average life limits remains, including a new test with a 2.25 year weighted average life limit that assumes a 50 percent slowdown in prepayment speeds to limit extension risk. The rule imposes new requirements concerning obtaining approval for proposed CUSO activities, and the rule also imposes new disclosure requirements concerning senior executive compensation, although the scope of the disclosure obligations under the final rule has been scaled back from the proposal.

Respondents: All federally insured corporate credit unions.

Estimated No. of Respondents/Record keepers: 27.

Estimated Burden Hours per Response: 3,887 hours, estimated as follows:

Capital restoration plans: 20 corporates × 50 hours = 1,000 hours.

Retained earnings accumulation Plans: 3 corporates × 50 hours = 150 hours.

Notice of intent to redeem contributed capital: 10 corporates × 1 hour = 10 hours.

Notice of PCA category change: 10 corporates × 1 hour = 10 hours.

Ratings procurement: 27 corporates × 2 hours = 54 hours.

Investment action plans: 10 corporates × 20 hours = 200 hours.

ALM testing: 27 corporates × 84 hours = 2,268 hours.

CUSO approval requests: 12 corporates × 2 hours = 24 hours.

Compensation disclosures: 27 corporates × 5 hours = 135 hours.

Merger related disclosures: 4 corporates × 5 hours = 20 hours.

Requests to make golden parachute and severance payments: 4 corporates × 4 hours = 16 hours.

Frequency of Response: Reporting, recordkeeping, on occasion, monthly, quarterly and annually.

Estimated Total Annual Burden Hours: 69,605 hours—revised based on revised estimate of burden hours.

Estimated Annual Cost: (Unchanged from initial estimate of \$8,500 per corporate.)

By the National Credit Union Administration Board on October 12, 2010.

Mary Rupp,

Secretary of the Board.

[FR Doc. 2010-26058 Filed 10-14-10; 8:45 am]

BILLING CODE 7535-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended), notice is hereby given that the following meetings of Humanities Panels will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Michael P. McDonald, Advisory

Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606-8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606-8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* November 1, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

2. *Date:* November 1, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for United States History in America's Media Makers Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

3. *Date:* November 2, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 415.

Program: This meeting will review applications for American Studies in Humanities Collections and Reference Resources, submitted to the Division of Preservation and Access at the July 15, 2010 deadline.

4. *Date:* November 2, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

5. *Date:* November 2, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for United States History in America's Media Makers Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

6. *Date:* November 3, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

7. *Date:* November 3, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for Western History in America's Historical and Cultural Organizations Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

8. *Date:* November 4, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

9. *Date:* November 4, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for Historic Sites in America's Historical and Cultural Organizations Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

10. *Date:* November 5, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

11. *Date:* November 8, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for World Cultures in America's Media Makers Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

12. *Date:* November 8, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions:

Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

13. *Date:* November 9, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs at the September 15, 2010 deadline.

14. *Date:* November 9, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for Radio and Digital Broadcasts in America's Media Makers Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

15. *Date:* November 9, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 415.

Program: This meeting will review applications for United States History and Culture III in Humanities Collections and Reference Resources, submitted to the Division of Preservation and Access at the July 15, 2010 deadline.

16. *Date:* November 10, 2010.

Time: 9 a.m. to 5 p.m.

Room: 421.

Program: This meeting will review applications for United States History in America's Historical and Cultural Organizations Grants Program, submitted to the Division of Public Programs at the August 18, 2010 deadline.

17. *Date:* November 10, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 415.

Program: This meeting will review applications for United States History and Culture IV in Humanities Collections and Reference Resources, submitted to the Division of Preservation and Access at the July 15, 2010 deadline.

18. *Date:* November 30, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 315.

Program: This meeting will review applications for Picturing America School Collaboration Projects, submitted to the Division of Education Programs at the October 7, 2010 deadline.

19. *Date:* November 30, 2010.

Time: 8:30 a.m. to 5 p.m.

Room: 415.

Program: This meeting will review applications for Art History in Humanities Collections and Reference Resources, submitted to the Division of

Preservation and Access at the July 15, 2010 deadline.

Michael P. McDonald,

Advisory Committee Management Officer.

[FR Doc. 2010-26007 Filed 10-14-10; 8:45 am]

BILLING CODE 7536-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that twelve meetings of the Arts Advisory Panel to the National Council on the Arts will be held at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 as follows (ending times are approximate):

Dance (application review): November 1-3, 2010 in Room 714. This meeting, from 9 a.m. to 6 p.m. each day, will be closed.

Arts Education (application review): November 1-5, 2010 in Room 716. A portion of this meeting, from 3:30 p.m. to 4 p.m. on November 4th, will be open to the public for a policy discussion. The remainder of the meeting, from 9 a.m. to 5:30 p.m. on November 1st through 3rd, from 9 a.m. to 3:30 p.m. and from 4 p.m. to 5:30 p.m. on November 4th and 9 a.m. to 5 p.m. on November 5th, will be closed.

Presenting (application review): November 2-3, 2010 in Room 730. This meeting, from 9 a.m. to 5:30 p.m. on November 2nd and from 9 a.m. to 3:45 p.m. on November 3rd, will be closed.

Presenting (application review): November 4-5, 2010 in Room 730. This meeting, from 9 a.m. to 5:30 p.m. on November 4th and from 9 a.m. to 4:15 p.m. on November 5th, will be closed.

Musical Theater (application review): November 4-5, 2010 in Room 714. This meeting, from 9 a.m. to 6 p.m. on November 4th and from 9 a.m. to 5 p.m. on November 5th, will be closed.

Media Arts (application review): November 8-9, 2010 in Room 716. This meeting, from 9 a.m. to 5:30 p.m. on November 8th and from 9 a.m. to 4:30 p.m. on November 10th, will be closed.

Music (application review): November 8-10, 2010 in Room 714. This meeting, from 9 a.m. to 5:30 p.m. on November 8th, from 9 a.m. to 6 p.m. on November 9th, and from 9 a.m. to 4:30 p.m. on November 10th, will be closed.

Local Arts Agencies (application review): November 9-10, 2010 in Room 730. This meeting, from 9 a.m. to 5:30 p.m. on November 9th and from 9 a.m.

to 2:30 p.m. on November 10th, will be closed.

Media Arts (application review): November 10, 2010 in Room 716. This meeting, from 9 a.m. to 3:30 p.m., will be closed.

Arts Education (application review): November 15-19, 2010 in Room 716. A portion of this meeting, from 9 a.m. to 10 a.m. on November 18th, will be open to the public for a policy discussion. The remainder of the meeting, from 9 a.m. to 5:30 p.m. on November 15th through 17th, from 10 a.m. to 5:30 p.m. on November 18th, and from 9 a.m. to 2 p.m. on November 19th, will be closed.

Theater (application review): November 16-19, 2010 in Room 714. A portion of this meeting, from 9 a.m. to 10 a.m. on November 18th, will be open to the public for a policy discussion. The remainder of the meeting, from 9 a.m. to 5:30 p.m. on November 16th, from 9 a.m. to 6 p.m. on November 17th, from 10 a.m. to 6 p.m. on November 18th, and from 9 a.m. to 3 p.m. on November 19th, will be closed.

Folk and Traditional Arts (application review): November 17-19, 2010 in Room 730. A portion of this meeting, from 2 p.m. to 3 p.m. on November 19th, will be open to the public for a policy discussion. The remainder of the meeting, from 9 a.m. to 5:30 p.m. on November 17th and 18th, and from 9 a.m. to 2 p.m. and 3 p.m. to 5 p.m. on November 19th, will be closed.

The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of November 10, 2009, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels that are open to the public, and if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman. If you need any accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TDY-TDD 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National

Endowment for the Arts, Washington, DC 20506, or call 202/682-5691.

Dated: October 12, 2010.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 2010-25993 Filed 10-14-10; 8:45 am]

BILLING CODE 7537-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services; Sunshine Act Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), NFAH.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the agenda of the forthcoming meeting of the National Museum and Library Services Board. This notice also describes the function of the Board. Notice of the meeting is required under the Sunshine in Government Act.

TIME AND DATE: Tuesday, October 19, 2010 from 9:30 a.m. until 12:30 p.m.

AGENDA: Twenty-First Meeting of the National Museum and Library Service Board.

- I. Welcome
- II. Approval of Minutes
- III. Financial Update
- IV. Legislative Update
- V. Board Program
- VI. Board Updates
- VII. Adjourn
(Open to the Public)

PLACE: The meeting will be held in the Board Room at the Institute of Museum and Library Services, 1800 M Street, NW., 9th Floor, Washington, DC 20036. Telephone: (202) 653-4676.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lyons, Director of Special Events and Board Liaison, Institute of Museum and Library Services, 1800 M Street, NW., 9th Floor, Washington, DC 20036. Telephone: (202) 653-4676 or e-mail: elyons@imls.gov.

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is established under the Museum and Library Services Act, 20 U.S.C. 9101 *et seq.* The Board advises the Director of the Institute on general policies with respect to the duties, powers, and authority of the Institute of Museum and Library Services, related to museum and library services.

If you need special accommodations due to a disability, please contact: Institute of Museum and Library Services, 1800 M Street, NW., 9th Fl.,

Washington, DC 20036. Telephone: (202) 653-4676; TDD (202) 653-4614 at least seven (7) days prior to the meeting date.

Dated: October 7, 2010.

Nancy E. Weiss,
General Counsel.

[FR Doc. 2010-26005 Filed 10-14-10; 8:45 am]

BILLING CODE 7036-01-M

NATIONAL INDIAN GAMING COMMISSION

Notice of Availability of the Record of Decision for Environmental Impact Statement for the Federated Indians of the Graton Rancheria Casino and Hotel, Sonoma County, CA

AGENCY: National Indian Gaming Commission (NIGC).

ACTION: Notice of Availability (NOA).

SUMMARY: In accordance with Section 102(2)(C) of the National Environmental Policy Act (NEPA) 42 U.S.C. 4321 *et seq.*, the NIGC, in cooperation with the Federated Indians of the Graton Rancheria (the "Graton Rancheria"), announces the availability of the Record of Decision (ROD) for the Federated Indians of the Graton Rancheria Casino and Hotel, Sonoma County, CA.

ADDRESSES: The document is available electronically on the following websites: <http://www.gratoneis.com>, http://www.nigc.gov/Environment_Public_Health_Safety/NEPA_Compliance.aspx. Hard copies of the document are available for viewing at the following addresses: Rohnert Park—Cotati Regional Library and Santa Rosa Central Library, general information, including directions and office hours is available online at: <http://www.sonoma.lib.ca.us/branches/> or by calling (707) 584-9121 for the Rohnert Park—Cotati Regional Library or (707) 545-0831 for the Santa Rosa Central Library.

FOR FURTHER INFORMATION CONTACT: For further information or to request a copy of the ROD, please contact: Brad Mehaffy, NEPA Compliance Officer, National Indian Gaming Commission, 1441 L Street, NW., Suite 9100, Washington, DC 20005.

Phone: (202) 632-7003, Ext. 256.

Fax: (202) 632-7066.

E-mail: bradley_mehaffy@nigc.gov.

SUPPLEMENTARY INFORMATION: The ROD covered by this Notice of Availability (NOA) is for the Federated Indians of the Graton Rancheria Casino and Hotel, Sonoma County, CA. The NIGC approves Alternative H-sub1 as the preferred alternative (see Attachment 3 of the ROD).

Authority: This notice is published in accordance with sections 1506.6 of the Council of Environmental Quality Regulations 40 CFR, parts 1500 through 1508 implementing the procedural requirements of the NEPA of 1969, as amended 42 U.S.C. 4371 *et seq.* This notice is also published in accordance with 40 CFR 93.155, which provides reporting requirements for conformity determinations.

Dated: October 8, 2010.

Tracie Stevens,
Chairwoman.

[FR Doc. 2010-26074 Filed 10-14-10; 8:45 am]

BILLING CODE 7565-01-P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: Under the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation invites the general public and other Federal agencies to take this opportunity to comment on this information collection.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; 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. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

DATES: Written comments should be received by December 14, 2010 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and

requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or by e-mail to splimpto@nsf.gov.

FOR ADDITIONAL INFORMATION OR

COMMENTS: Contact Suzanne Plimpton, the NSF Reports Clearance Officer, phone (703) 292-7556, or send e-mail to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title: Major Research Instrumentation (MRI) Program. Outcomes Survey.

OMB Approval Number: 3145-NEW.

Expiration Date of Approval: Not applicable.

Abstract

The Major Research Instrumentation Program (MRI) catalyzes new knowledge and discoveries by providing the Nation's scientists and engineers with state-of-the-art research instrumentation. The MRI Program enables research-intensive learning environments that promote the development of a diverse workforce and next generation instrumentation, as well as facilitates academic/private sector partnerships. Among the goals of the MRI Program are:

- Supporting the acquisition of major state-of-the-art instrumentation, thereby improving access to, and increased use of, modern research and research training instrumentation by a diverse workforce of scientists, engineers, and graduate and undergraduate students;
- Fostering the development of the next generation of instrumentation, resulting in new instruments that are more widely used, and/or open up new areas of research and research training;
- Enabling academic departments, disciplinary and cross-disciplinary units organizations and multi-organization collaborations to create well-equipped research environments that integrate research with education;
- Supporting the acquisition and development of instrumentation that contributes to, or takes advantage of, existing investments in cyberinfrastructure, while avoiding duplication of services already provisioned by NSF investments; and
- Promoting substantive and meaningful partnerships for instrument development between the academic and private sectors. Such partnerships have

the potential to build capacity for instrument development in academic settings and to create new products with wide scientific and commercial impact.

The MRI program is seeking OMB approval to administer a comprehensive survey of all MRI awardees to better understand outcomes from the program.

Expected Respondents

The respondents will be current and former MRI awardees all based at academic and non-profit organizations. Quantitative procedures will be fielded using Web-based modes. Up to 3,600 MRI awardees (respondents) will be contacted to request their participation in the survey. As needed, each MRI awardee will be contacted with reminders to complete the survey no more than twice during the survey's duration under this generic clearance. Technology will be heavily utilized to limit the burden on respondents.

Use of the Information

The purpose of this survey of MRI awardees is to better understand outcomes of NSF MRI-related investments. The data will be used internally to inform NSF as it considers future improvements to the MRI program, and to gain a better understanding regarding the program's impact on associated research and education activities. Findings may be presented externally in technical papers at conferences, published in the proceedings of conferences, or in journals.

Burden on the Public

Number of Respondents: 3600.

Number of Minutes per Response: 30.

Overall Burden Request (in hours): 1800.

Dated: October 12, 2010.

Suzanne Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2010-26020 Filed 10-14-10; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No.: 40-8905; NRC-2010-0326]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment No. 61 for Rio Algom Mining LLC, Ambrosia Lake, NM—SUA-1473

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT:

Thomas McLaughlin, Project Manager, Materials Decommissioning Branch, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415-5869; fax number: (301) 415-5369; e-mail:

Thomas.McLaughlin@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Source Materials License SUA-1473 issued to Rio Algom Mining LLC (Rio Algom, or the Licensee) to authorize an alternate on-site disposal cell location for disposal of byproduct material at its Ambrosia Lake Mill Facility, in Ambrosia Lake, New Mexico. The NRC has prepared an Environmental Assessment (EA) for this proposed action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued following the publication of this Notice.

The Licensee previously has addressed, and the NRC has approved, the remaining site-wide reclamation plan elements through separate licensing actions, including the original reclamation plan for Tailings Ponds 1, 2, and 3 Disposal Cells (approved in September 1990), mill demolition, relocation of lined evaporation pond sediments, soil decommissioning plan, and groundwater remediation. The expansion of Tailings Pond Disposal Cell 2 was approved by License Amendment No. 58. The current licensing action is to provide an alternate on-site disposal area for placing byproduct material such as mill building debris and windblown impacted soil.

II. Environmental Assessment Summary

The purpose of the proposed amendment is to authorize an alternate on-site disposal cell location at the Licensee's Ambrosia Lake Mill Facility, in Ambrosia Lake, New Mexico. By letter dated April 26, 2010, Rio Algom submitted a request to the NRC for approval of an alternate on-site disposal cell location for disposal of byproduct material.

Rio Algom proposes placing byproduct materials, consisting

primarily of mill building debris and windblown impacted soils, in the former ore-storage area west of the existing mill office, and stabilizing the materials in accordance with NRC standards in 10 CFR part 40. The cover over the disposal area would consist of a radon/infiltration barrier, overlain by a frost protection layer and rock erosion protection layers. Following approval by NRC of successful remediation of the area pursuant to the Reclamation Plan, the construction will be completed and the site eventually will be transferred to DOE.

The staff, in coordination with the New Mexico Environmental Department (NMED), has prepared the EA in support of the proposed license amendment. The EA evaluates the construction of an alternate on-site disposal cell and is limited to the construction impacts as all other impacts (long-term and indirect) were previously evaluated in the Tailings Pond 2 expansion EA completed in November 2007, in connection with License Amendment No. 58.

The potential direct impacts from construction activities primarily would be dust generation due to excavating material to form the channel, noise generated by construction equipment, and water surface runoff. The staff has determined that these potential direct impacts would be sufficiently mitigated, and the potential impacts at the tailings cell area would be small as the area is already disturbed from site reclamation activities.

Three alternatives to the proposed action were considered and rejected, including: no action, increasing the capacity of disposal area #2, or selecting another disposal area at the facility.

II. Finding of No Significant Impact

Based on the analysis contained in this EA, the staff concluded that there are no significant environmental impacts from the proposed action, and that the preparation of an Environmental Impact Statement is not warranted. Accordingly, the NRC determined that a Finding of No Significant Impact is appropriate.

III. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public

documents. The ADAMS accession numbers for the documents related to this notice are: the Licensee's license amendment request and environmental evaluation dated April 26, 2010 (ADAMS ML101190534); the October 1, 2010, EA for License Amendment No. 61 (the alternate on-site disposal cell location) (ADAMS ML102220253); Approval for License Amendment No. 58 (ADAMS ML073050328); and the November 2007, EA for Tailings Pond 2 (ADAMS ML072670278). If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@nrc.gov.

These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland, this 7th day of October, 2010.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2010-25996 Filed 10-14-10; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[NRC-2009-0435]

Notice of Availability of Draft Environmental Assessment and Draft Finding of No Significant Impact and Notice of Public Meeting for the Proposed License Renewal for Nuclear Fuel Services, Inc. in Erwin, TN

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability of Draft Environmental Assessment and Draft Finding of No Significant Impact; Notice of public meeting.

SUMMARY: Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment the Draft Environmental Assessment (EA) and Draft Finding of No Significant Impact (FONSI) for the proposed renewal of NRC special nuclear material license SNM-124 (License SNM-124) that authorizes operations at the Nuclear Fuel Services, Inc. (NFS) fuel fabrication facility in

Erwin, Tennessee. On June 30, 2009, NFS submitted to the NRC an application in which NFS requested renewal of License SNM-124 for a 40-year period.

The Draft EA and Draft FONSI are being issued for public review and comment based on the NRC staff determination that (1) the NFS proposed action to renew License SNM-124 for 40 years is without precedent, because, if granted, this would be the first 40-year license renewal for a Category I nuclear fuel fabrication facility, and (2) the preparation of a Draft EA and Draft FONSI will further the purposes of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*).

The NRC staff's environmental review of the proposed 40-year license renewal is documented in the Draft EA, which was prepared following NRC regulations at title 10 of the U.S. Code of Federal Regulations (10 CFR) part 51 that implement NEPA, and in accordance with NRC staff guidance in NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." In the Draft EA, the NRC staff identifies and evaluates the potential environmental impacts of the proposed renewal of License SNM-124 and any reasonable alternatives. Based on the Draft EA, the NRC staff has made a preliminary determination that renewal of License SNM-124 for a 40-year period will not significantly affect the quality of the human environment and that a finding of no significant impact should therefore be made. By this notice, the NRC staff is requesting public comment on the Draft FONSI and on the supporting Draft EA.

The NRC staff will hold a public meeting on October 26, 2010, to accept oral and written public comments on the Draft FONSI and Draft EA. The meeting will take place at the Erwin Town Hall in Erwin, Tennessee. For one hour prior to the public meeting, the NRC staff will be available to informally discuss the proposed action and answer questions in an "open house" format. The public meeting will officially begin at 6 p.m. The meeting will include (1) NRC staff presentations summarizing the NRC's roles and responsibilities with respect to the proposed license renewal and also the contents of the Draft EA that supports the Draft FONSI, and (2) an opportunity for interested government agencies, Tribal governments, organizations, and individuals to provide oral or written comments on the Draft EA and Draft FONSI. The public meeting will be transcribed by a court reporter, and the

meeting transcript will be made publicly available at a later date.

Persons wishing to provide oral comments at the public meeting may register in advance by contacting Ms. Tarsha Moon at (800) 368-5642, ext. 6745, no later than October 22, 2010. Those who wish to present oral comments may also register at the meeting. Individual oral comments may have to be limited by the time available, depending upon the number of persons who register. Written comments can also be provided at the meeting, and should be given to an NRC staff person at the registration desk at the meeting entrance. If special equipment or accommodations are needed to attend or present information at the public meeting, the need should be brought to the attention of Ms. Tarsha Moon at (800) 368-5642, ext. 6745, no later than October 22, 2010, to provide NRC staff with adequate notice to determine whether the request can be accommodated. Please note that comments do not have to be provided at the public meeting and may be submitted at any time during the comment period, as described in the **DATES** section of this notice. Any interested party may submit comments on the Draft EA and Draft FONSI for consideration by NRC staff. Comments may be submitted by any of the methods described in the **ADDRESSES** section of this notice.

DATES: The public comment period on the Draft FONSI and the Draft EA begins on the date of publication of this notice and ends on November 13, 2010. To ensure consideration, comments on the Draft FONSI and Draft EA must be received or postmarked by November 13, 2010. The NRC staff will consider comments received or postmarked after that date to the extent practical.

The NRC will conduct a public meeting in Erwin, Tennessee. The meeting date, time, and location are listed below:

Meeting Date: October 26, 2010.

Meeting Location: Erwin Town Hall, 211 North Main, Avenue, Erwin, Tennessee 37650.

Informal Open House Session: 5-6 p.m.

Public Comment Meeting: 6-9 p.m.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC-2009-0435 in the subject line of your comments.

Electronic Mail: Comments may be sent by electronic mail to the following address: NuclearFuel_DraftEA@nrc.gov.

Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search

for documents filed under Docket ID NRC-2009-0435. Comments may be submitted electronically through this Web site. Address questions about NRC dockets to Carol Gallagher at 301-492-3668, or e-mail at

Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to RADB at (301) 492-3446.

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site <http://www.regulations.gov>. Unless your comments contain sensitive information typically not released to the public by NRC policy, the NRC will make all comments publically available. Because your comments will not be edited to remove any identifying information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Document Availability: Publicly available documents related to this notice can be accessed using any of the methods described in this section.

NRC's Public Document Room (PDR): The public may examine and have copied, for a fee, publicly available documents related to the NFS facility and license renewal at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Members of the public can contact the NRC's PDR reference staff by calling 1-800-397-4209, by faxing a request to 301-415-3548, or by e-mail to pdr.resource@nrc.gov. Hard copies of the documents are available from the PDR for a fee.

NRC's Agencywide Documents Access and Management System (ADAMS): Members of the public can access the NRC's ADAMS at <http://www.nrc.gov/reading-rm/adams.html>. From this Web site, the following documents related to the NRC's environmental review can be obtained by entering the accession numbers provided:

- The NFS license renewal application (ADAMS Accession Number: ML091880040) and the accompanying Environmental Report (ADAMS Accession Number: ML091900072),
- The NRC request for additional information (ADAMS Accession Number: ML100680426),
- The NFS response providing additional information (ADAMS Accession Number: ML101590160), and
- The NRC Draft FONSI (ADAMS Accession Number: ML102790260) and supporting Draft EA (ADAMS Accession Number: ML102650505).

Federal Rulemaking Web site: Public comments and supporting materials related to this notice can be found at <http://www.regulations.gov> by searching on Docket ID: NRC-2009-0435.

Additionally, copies of the Draft FONSI and supporting Draft EA will be available at the following public libraries:

- Unicoi County Public Library, 201 Nolichucky Avenue, Erwin, Tennessee 37650-1239. 423-743-6533.
- Jonesborough Branch, Washington County Library, 200 Sabin Drive, Jonesborough, Tennessee 37659-1306. 423-753-1800.
- Greeneville/Green County Public Library, 210 North Main Street, Greeneville, Tennessee 37745-3816. 423-638-5034.

FOR FURTHER INFORMATION CONTACT: For information about the Draft FONSI, the Draft EA, or the environmental review process, please contact James Park at (301) 415-6935 or James.Park@nrc.gov. For general or technical information associated with the review of the NFS license renewal application, please contact Kevin Ramsey at (301) 492-3123 or Kevin.Ramsey@nrc.gov.

SUPPLEMENTARY INFORMATION: On June 30, 2009, NFS submitted an application and accompanying environmental report to the NRC to request renewal of License SNM-124. On October 6, 2009, the NRC provided notice in the **Federal Register** (74 FR 51323) of its receipt of the license renewal application and also noticed an opportunity to request a hearing on the application; no requests for a hearing were received. Under the conditions of License SNM-124, NFS operates a nuclear fuel fabrication facility located in Erwin, Tennessee. If granted as proposed, the renewed license would allow NFS to continue operations and activities at the site for a 40-year period to begin with issuance of the renewed license.

The NRC staff prepared the Draft EA following NRC regulations at 10 CFR

part 51 that implement NEPA. Preparation of the Draft EA is part of the NRC's process to decide whether to renew the NFS license, pursuant to 10 CFR parts 20 and 70, and thus authorize continued operations at the NFS facility. In accordance with the provisions of 10 CFR part 70, the current license authorizes NFS to receive, possess, store, use, and ship SNM enriched up to 100 percent. Under the proposed action analyzed in the Draft EA, NFS would continue production of reactor fuel for government operations and for commercial domestic operations.

In addition to NFS' proposed action to renew its license for 40 years, the NRC staff analyzed two alternatives: (1) The no-action alternative, and (2) renewing the NFS license for 10 years. Under the no-action alternative, NRC would not renew License SNM-124, and as a result, operations at the NFS site would be required to cease. Also, NFS would be required under 10 CFR 70.38 to submit a detailed site decommissioning plan, and facility decommissioning would begin upon NRC approval of that plan. NRC's review would address both the health and safety and the environmental aspects of the proposed decommissioning plan.

NRC considered a 10-year license renewal period as an alternative. A period of 10 years was chosen as an alternative because the license was previously renewed for this time period. The NRC staff did not separately address the 10-year alternative throughout the Draft EA, because the staff determined that the site operations and the types of potential impacts during a 10-year license renewal period would be expected to be the same for the proposed 40-year license renewal period. Additionally, the significance of the potential impacts also would be the same under the 10-year renewal alternative even though proportionally, the impacts would be reduced for certain environmental resource areas (*i.e.*, for transportation, public and occupational health, and waste management) under that alternative.

The table below summarizes the potential environmental impacts for each of the three alternatives. Using guidance in NUREG-1748, the NRC staff evaluated the potential impacts and then categorized the impacts as follows:

- **SMALL**—environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource;
- **MODERATE**—environmental effects are sufficient to alter noticeably, but not to destabilize, important attributes of the resource; or

- LARGE—environmental effects are clearly noticeable and are sufficient to destabilize important attributes of the resource.

SUMMARY OF POTENTIAL ENVIRONMENTAL IMPACTS

| Resource area | Proposed action (40-Year Renewal) | 10-Year renewal | No-action |
|---|---|---|------------------------------------|
| Land Use | SMALL | SMALL | MODERATE. |
| Transportation | SMALL (overall), MODERATE (local). | SMALL (overall), MODERATE (local). | SMALL (overall), MODERATE (local). |
| Socioeconomics | SMALL | SMALL | SMALL to MODERATE. |
| Air Quality | SMALL | SMALL | SMALL. |
| Water Resources—Surface Water | SMALL | SMALL | SMALL to MODERATE. |
| Water Resources—Groundwater | SMALL to MODERATE | SMALL to MODERATE | SMALL to MODERATE. |
| Geology & Soils | SMALL (geology), SMALL to MODERATE (soils). | SMALL (geology), SMALL to MODERATE (soils). | SMALL (geology), MODERATE (soils). |
| Ecology | SMALL | SMALL | SMALL to MODERATE. |
| Noise | SMALL | SMALL | SMALL to MODERATE. |
| Historic & Cultural | SMALL | SMALL | SMALL. |
| Scenic & Visual | SMALL | SMALL | MODERATE. |
| Public & Occupational Health | SMALL | SMALL | SMALL. |
| Public & Occupational Health—Accidents. | SMALL to MODERATE | SMALL to MODERATE | SMALL. |
| Waste Management | SMALL | SMALL | MODERATE. |

Based on its review of the proposed action relative to the requirements set forth in 10 CFR part 51, the NRC staff has preliminarily determined that renewal of License SNM-124, which would authorize operations at NFS's nuclear fuel fabrication facility in Erwin, Tennessee to continue for a period of 40 years would not significantly affect the quality of the human environment. The facility already exists, and no changes to the site or to facility operations are associated with the proposed license renewal. As such, the proposed action can be considered a continuation of impacts and was evaluated based on impacts from past operations. Gaseous emissions and liquid effluents are controlled and monitored by permit and are within regulatory limits for non-radiological and radiological components. Public and occupational radiological dose exposures are below 10 CFR part 20 regulatory limits. Therefore, based on this preliminary assessment, an Environmental Impact Statement (EIS) is not warranted, and pursuant to 10 CFR 51.31, a Finding of No Significant Impact is appropriate.

The Draft FONSI and supporting Draft EA are a preliminary analysis of the environmental impacts of the proposed action and its alternatives. Based on comments received on the Draft FONSI and Draft EA, the staff may publish a Final FONSI and Final EA, or instead may find that preparation of an EIS is warranted should significant impacts resulting from the proposed action be identified. Should an EIS be warranted, a Notice of Intent to prepare the EIS will be published in the **Federal Register**.

Pursuant to 10 CFR 51.33(a), the NRC staff is making the Draft FONSI and Draft EA available for public review and comment. The public comment period begins with publication of this Notice and continues until November 13, 2010. Written comments should be submitted as described in the **ADDRESSES** section of this notice. The NRC will consider comments received or postmarked after that date to the extent practical.

Dated at Rockville, Maryland, this 8th day of October, 2010.

For the Nuclear Regulatory Commission,
David Skeen,
Acting Deputy Director, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2010-25997 Filed 10-14-10; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52-043; NRC-2010-0215]

PSEG Power, LLC and PSEG Nuclear, LLC; PSEG Site Early Site Permit Application, Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping Process

PSEG Power, LLC and PSEG Nuclear, LLC have submitted an application for an early site permit (ESP) for the PSEG Site, which is located on the southern part of Artificial Island on the east bank of the Delaware River in Lower Alloways Creek Township, Salem

County, New Jersey. The application for the ESP was submitted by PSEG Power, LLC and PSEG Nuclear, LLC by letter dated May 25, 2010, pursuant to Title 10 of the Code of Federal Regulations (10 CFR), Part 52.

A notice of receipt and availability of the application including the environmental report (ER) was published in the **Federal Register** on June 18, 2010 (75 FR 34794). A notice of acceptance for docketing of the application for the ESP was published in the **Federal Register** on August 13, 2010 (75 FR 49539). A notice of hearing and opportunity to petition for leave to intervene will be published at a later date.

The purposes of this notice are (1) to inform the public that the U.S. Nuclear Regulatory Commission (NRC) will be preparing an environmental impact statement (EIS) as part of the review of the ESP application and (2) to provide the public with an opportunity to participate in the environmental scoping process as defined in 10 CFR 51.29. The NRC intends to invite the U.S. Army Corps of Engineers, Philadelphia District, to participate in the preparation of the EIS as a cooperating agency. The purpose of cooperation with the Corps is to develop an environmental impact statement that serves the needs of the NRC license decision process and the Corps' permit decision process. Also, to comply with Section 106 of the National Historic Preservation Act, the NRC staff intends to use the procedures outlined in 36 CFR 800.8(c) for the preparation of the EIS on the proposed action, in lieu of

the procedures set forth at 36 CFR 800.3 through 800.6.

In accordance with 10 CFR 51.45 and 51.50, PSEG Power, LLC and PSEG Nuclear, LLC submitted the ER as part of the ESP application. The ER was prepared pursuant to 10 CFR parts 51 and 52 and is available for public inspection at the NRC Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852 or from the Publicly Available Records (PAR) component of NRC Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible at <http://www.nrc.gov/reading-rm/adams.html>, which provides access through the NRC Electronic Reading Room (ERR) link. The accession number in ADAMS for the environmental report is ML101480763. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff at 1-800-397-4209/301-415-4737 or via e-mail to pdr.resource@nrc.gov. The application may also be viewed on the Internet at <http://www.nrc.gov/reactors/new-reactors/esp/pseg.html>. In addition, the Penns Grove-Carneys Point Public Library, Penns Grove, New Jersey, the Pennsville Public Library, Pennsville, New Jersey and the Salem Free Public Library, Salem, New Jersey, have each agreed to maintain a copy of the ER and make it available for public inspection.

The following key reference documents related to the application and the NRC staff's review processes are available through the NRC Web site at <http://www.nrc.gov>:

- a. 10 CFR part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,
- b. 10 CFR part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants,
- c. 10 CFR part 100, Reactor Site Criteria,
- d. NUREG-1555, Standard Review Plans for Environmental Reviews for Nuclear Power Plants,
- e. NUREG/BR-0298, Brochure on Nuclear Power Plant Licensing Process,
- f. Regulatory Guide 4.2, Preparation of Environmental Reports for Nuclear Power Stations,
- g. Regulatory Guide 4.7, General Site Suitability Criteria for Nuclear Power Stations,
- h. Fact Sheet on Nuclear Power Plant Licensing Process,
- i. Regulatory Guide 1.206, Combined License Applications for Nuclear Power Plants, and

j. Nuclear Regulatory Commission Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions.

The regulations, NUREG-series documents, regulatory guides, and the fact sheet can be found under Document Collections in the ERR on the NRC webpage. The environmental justice policy statement can be found in the **Federal Register**, 69 FR 52040, August 24, 2004.

This notice advises the public that the NRC intends to gather the information necessary to prepare an EIS as part of the review of the application for the ESP at the PSEG Site. Possible alternatives to the proposed action (issuance of the ESP for the PSEG site) include no action and alternative sites. This notice is being published in accordance with NEPA and the NRC regulations found in 10 CFR part 51. As set forth in 10 CFR 51.20(b)(1), issuance of a ESP under 10 CFR part 52 is an action that requires an EIS.

The NRC will first conduct a scoping process for the EIS and thereafter will prepare a draft EIS for public comment. Participation in this scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the draft EIS will be used to accomplish the following:

- a. Define the proposed action that is to be the subject of the EIS,
- b. Determine the scope of the EIS and identify the significant issues to be analyzed in depth,
- c. Identify and eliminate from detailed study those issues that are peripheral or that are not significant,
- d. Identify any environmental assessments and other EISs that are being or will be prepared that are related to but are not part of the scope of the EIS being considered,
- e. Identify other environmental review and consultation requirements related to the proposed action,
- f. Identify parties consulting with the NRC under the NHPA, as set forth in 36 CFR 800.8(c)(1)(i),
- g. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decision-making schedule,
- h. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the EIS to the NRC and any cooperating agencies; and
- i. Describe how the EIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in the scoping process:

a. The applicant, PSEG Power, LLC and PSEG Nuclear, LLC,

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards,

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards,

d. Any affected Indian tribe,

e. Any person who requests or has requested an opportunity to participate in the scoping process; and

f. Any person who intends to petition for leave to intervene.

In accordance with 10 CFR 51.26, the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to a proposed activity and to determine the scope of issues to be addressed in an EIS. The NRC staff has elected to hold two identical public scoping meetings at the Performing Arts Theater (Davidow Hall), on the campus of Salem Community College (460 Hollywood Avenue, Carneys Point, New Jersey) on Thursday, November 4, 2010. The first meeting will convene at 1 p.m., and will continue until approximately 4 p.m. The second meeting will convene at 7 p.m. and will continue until approximately 10 p.m. The meetings will be transcribed and will include the following: (1) An overview by the NRC staff of the environmental review process, the proposed scope of the EIS, and the proposed review schedule; (2) an opportunity for interested government agencies, organizations, and individuals to submit comments on the environmental issues or the proposed scope of the EIS. Additionally, the NRC staff will host informal discussions for one hour prior to the start of each public meeting. No formal comments on the proposed scope of the EIS will be accepted during the informal discussions. To be considered, comments must be provided either at the transcribed public meeting or in writing, as discussed below. Persons may register to attend or present oral comments at the meeting on the scope of the EIS by contacting Mr. Allen H. Fetter or Ms. Alicia Williamson at 1-800-368-5642, extensions 8556 or 1878, respectively. In addition, persons can register via e-mail to the NRC at PSEGSite.ESPEIS@nrc.gov no later than November 1, 2010.

Members of the public may also register to speak at the meetings prior to the start of each session. Individual oral comments may be limited by the time available, depending on the number of

persons who register. Members of the public who have not registered may also have an opportunity to speak, if time permits. Public comments will be considered in the scoping process for the EIS. If special equipment or accommodations are needed to attend or present information at the public meeting, such requests should be brought to Mr. Fetter's or Ms. Williamson's attention no later than October 27, 2010, so that the NRC staff can determine whether the request can be accommodated.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC-2010-0215 in the subject line of your comments.

Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2010-0215. Comments may be submitted electronically through this Web site. Address questions about NRC dockets to Carol Gallagher at 301-492-3668, or e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Members of the public may send written comments on the scope of the PSEG Site ESP environmental review to Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to RADB at (301) 492-3446. To be considered in the scoping process, written comments must be postmarked or delivered by the comment period end date of December 14, 2010. Electronic comments may be sent by e-mail to the NRC at PSEGSite.ESPEIS@nrc.gov. Electronic submissions must be received no later than the comment period end date of December 14, 2010, to be considered in the scoping process.

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site <http://www.regulations.gov>. Unless your comments contain sensitive information typically not released to the public by NRC policy, the NRC will make all comments publically available. Because your comments will not be edited to remove any identifying information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those

persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Document Availability: Publicly available documents related to this notice can be accessed using any of the methods described in this section.

Participation in the scoping process for the EIS does not entitle participants to become parties to the proceeding to which the EIS relates. Notice of a hearing regarding the application for COLs will be noticed separately in the **Federal Register**.

At the conclusion of the scoping process, the NRC will prepare a concise summary of the determination and conclusions on the scope of the environmental review including the significant issues identified and will make this summary publicly available. The staff will then prepare and issue for comment the draft EIS which will be the subject of a separate **Federal Register** notice and a separate public meeting. Copies of the draft EIS will be available for public inspection at the PDR through the above-mentioned address and one copy per request will be provided free of charge. After receipt and consideration of the comments, the NRC will prepare a final EIS, which will also be available to the public. Information about the proposed action, the EIS, and the scoping process may be obtained from Mr. Allen Fetter or Ms. Alicia Williamson at the U.S. Nuclear Regulatory Commission, Mail Stop T7-E18, Washington, DC 20555-0001, by phone at 1-800-368-5642, extensions 8556 or 1878, respectively or via e-mail to Allen.Fetter@nrc.gov or Alicia.Williamson@nrc.gov.

Dated at Rockville, Maryland, this 8th day of October 2010.

For the Nuclear Regulatory Commission.

Scott Flanders,

Director, Division of Site and Environmental Reviews, Office of New Reactors.

[FR Doc. 2010-25998 Filed 10-14-10; 8:45 am]

BILLING CODE 7590-01-P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service Appointments

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This gives notice of OPM decisions granting authority to make appointments under Schedules A, B,

and C in the excepted service as required by 5 CFR 213.103.

FOR FURTHER INFORMATION CONTACT:

Roland Edwards, Manager, Senior Executive Resource Services, Employee Services, 202-606-2246.

SUPPLEMENTARY INFORMATION: Appearing in the listing below are the individual authorities established under Schedules A, B, and C between August 1, 2010, and August 31, 2010. These notices are published monthly in the **Federal Register** at <http://www.gpoaccess.gov/fr/>. A consolidated listing of all authorities as of June 30 is also published each year. The following Schedules are not codified in the Code of Federal Regulations. These are agency-specific exceptions.

Schedule A

Schedule A authorities to report during August 2010.

Department of Treasury (Section 213.3105)

(a)(2) Covering no more than 100 positions supplementing permanent staff studying domestic economic and financial policy, with employment not to exceed 4 years.

Schedule B

No Schedule B authorities to report during August 2010.

Schedule C

The following Schedule C appointments were approved during August 2010.

Office of National Drug Control Policy

QQGS90006 Outreach and Events Coordinator for Intergovernmental Affairs. Effective August 19, 2010.

Office of the United States Trade Representative

TNGS00036 Confidential Assistant to the Chief of Staff. Effective August 2, 2010.

TNGS00037 Director of Scheduling and Advance to the United States Trade Representative. Effective August 2, 2010.

Department of State

DSGS70094 Protocol Assistant to the Chief of Protocol. Effective August 16, 2010.

DSGS70117 Legislative Management Officer for Legislative and Intergovernmental Affairs. Effective August 16, 2010.

Department of the Treasury

DYGS00518 Spokesperson for the Public Affairs Operations. Effective August 10, 2010.

DYGS60277 Senior Speechwriter for Public Affairs. Effective August 17, 2010.

Department of Defense

DDGS17291 Special Assistant to the Deputy Assistant Secretary of Defense (Industrial Policy). Effective August 10, 2010.

DDGS17294 Defense Fellow of Defense for the White House Liaison. Effective August 13, 2010.

DDGS17295 Defense Fellow for the White House Liaison. Effective August 13, 2010.

DDGS17296 Defense Fellow for the White House Liaison. Effective August 13, 2010.

DDGS17206 Special Assistant to the Deputy Assistant Secretary of Defense (Budget and Appropriations Affairs). Effective August 17, 2010.

DDGS17293 Staff Assistant for the White House Liaison. Effective August 24, 2010.

Department of the Air Force

DFGS60027 Special Assistant to the Secretary of the Air Force. Effective August 23, 2010.

DFGS60028 Special Assistant to the Assistant Secretary (Installations, Environment and Logistics). Effective August 23, 2010.

Department of Justice

DJGS00499 Confidential Assistant for the Office on Violence Against Women. Effective August 2, 2010.

DJGS00357 Confidential Assistant to the Deputy Attorney General. Effective August 11, 2010.

DJGS00617 Counsel to the Assistant Attorney General. Effective August 13, 2010.

DJGS00618 Counsel for Access to Justice. Effective August 13, 2010.

DJGS00619 Special Assistant to the Attorney General. Effective August 13, 2010.

DJGS00494 Counsel to the Assistant Attorney General. Effective August 16, 2010.

DJGS00620 Attorney Advisor to the Assistant Attorney General (Legislative Affairs). Effective August 26, 2010.

Department of the Interior

DIGS01198 Deputy Director, Intergovernmental Affairs. Effective August 5, 2010.

DIGS01200 Special Assistant of Ocean Energy Management, Regulation and Enforcement. Effective August 10, 2010.

Department of the Interior

DIGS01185 Deputy Chief of Staff for Land and Minerals Management. Effective August 13, 2010.

Department of Agriculture

DAGS00240 Confidential Assistant for Risk Management. Effective August 26, 2010.

Department of Commerce

DCGS00339 Confidential Assistant for Legislative and Intergovernmental Affairs. Effective August 5, 2010.

DCGS00330 Senior Director for Administration. Effective August 10, 2010.

DCGS00184 Special Assistant to the General Counsel. Effective August 11, 2010.

DCGS00657 Confidential Assistant to the Deputy Chief of Staff. Effective August 20, 2010.

DCGS00298 Special Advisor for Antidumping and Countervailing Duty Policy and Negotiations. Effective August 25, 2010.

Department of Labor

DLGS60141 Special Assistant for Labor-Management Programs. Effective August 2, 2010.

DLGS60253 Special Assistant to the Deputy Chief of Staff. Effective August 2, 2010.

DLGS60122 Senior Advisor for Policy. Effective August 9, 2010.

Department of Health and Human Services

DHGS60257 Special Assistant of Intergovernmental Affairs. Effective August 10, 2010.

DHGS60344 Confidential Assistant for Legislation (Health Policy). Effective August 13, 2010.

DHGS60570 Confidential Assistant (Advance) for Advance. Effective August 13, 2010.

DHGS60331 Special Assistant for Centers for Medicare and Medicaid Services. Effective August 16, 2010.

Department of Education

DBGS00250 Confidential Assistant to the Under Secretary. Effective August 16, 2010.

DBGS00212 Confidential Assistant for Postsecondary Education. Effective August 20, 2010.

Environmental Protection Agency

EPGS05018 Deputy Associate Administrator for Office of Congressional Affairs. Effective August 20, 2010.

Council on Environmental Quality

EQGS10011 Special Assistant to the Chairman (Council on Environmental Quality). Effective August 2, 2010.

Federal Communications Commission

FCGS10228 Advisor to the Chairman. Effective August 17, 2010.

Department of Energy

DEGS00826 Special Assistant to the Chief of Staff. Effective August 3, 2010.

DEGS00827 Legislative Policy Advisor for Congressional and Intergovernmental Affairs. Effective August 3, 2010.

Small Business Administration

SBSGS00681 Special Assistant for Capital Access. Effective August 10, 2010.

SBSGS00684 Senior Advisor for Entrepreneurial Development. Effective August 17, 2010.

National Credit Union Administration

CUOT91417 Staff Assistant to a Board Member. Effective August 5, 2010.

Department of Housing and Urban Development

DUGS00024 Special Assistant for Operations. Effective August 5, 2010.

DUGS00040 Congressional Relations Specialist for Congressional and Intergovernmental Relations. Effective August 10, 2010.

Department of Transportation

DTGS60351 Counselor to the Deputy Secretary. Effective August 2, 2010.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1954-1958 Comp., p. 218.

Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2010-26084 Filed 10-14-10; 8:45 am]

BILLING CODE 6325-39-P

RAILROAD RETIREMENT BOARD

Computer Matching and Privacy Protection Act of 1988; Report of Matching Program: RRB and State Medicare Agencies

AGENCY: Railroad Retirement Board (RRB).

ACTION: Notice of records used in computer matching programs; Notification to individuals who are beneficiaries under the Railroad Retirement Act.

SUMMARY: As required by the Computer Matching and Privacy Protection Act of

1988, the RRB is issuing a public notice of its use and intent to use, in ongoing computer matching programs. In this match, we provide certain Medicare and benefit rate information to state agencies to adjust amounts of benefits in their public assistance programs as well as to coordinate Medicare/Medicaid payments for public assistance recipients.

The purpose of this notice is to advise individuals receiving benefits under the Railroad Retirement Act of the disclosure through a computer match that RRB plans to share with state agencies.

DATES: Submit comments on or before November 24, 2010.

ADDRESSES: Address any comments concerning this notice to Beatrice Ezerski, 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 number (312) 751-4869 or e-mail at tim.grant@rrb.gov.

SUPPLEMENTARY INFORMATION: Under certain circumstances, the Computer Matching and Privacy Protection Act of 1988, Public Law 100-503, requires a Federal agency participating in a computer matching program to publish a notice in the **Federal Register** regarding the establishment of that matching program. Such a notice must include information in the following first five categories:

Name of Participating Agencies: The Railroad Retirement Board and state public aid/public assistance agencies.

Purpose of the Match: The match has several purposes to enable the state agency to:

- (1) Accurately identify Qualified Railroad Retirement Beneficiaries;
- (2) Make necessary adjustments required under state law in public aid payments due to cost of living or other adjustments in RRB annuities;
- (3) Coordinate benefits of dually eligible Medicare and Medicaid beneficiaries; and

(4) To identify individuals who are eligible for Part B Medicare and not enrolled in order to enroll such individuals in the State Buy-In program.

Authority for Conducting the Match: 20 CFR 200.5(j)(1), 20 CFR 200.8(g)(10), 42 CFR 435.940 through 435.965.

Categories of Records and Individuals Covered: All beneficiaries under the Railroad Retirement Act who have been identified by a state as a recipient of public aid will have information about their RRB benefits and Medicare

enrollment furnished to the requesting state agency. This information is covered as a routine disclosure under either the Privacy Act system of records RRB-20, Health Insurance and Supplementary Medical Insurance Enrollment and Premium Payment System (MEDICARE), or RRB-21, Railroad Unemployment and Sickness Insurance Benefit System.

Inclusive Dates of the Matching Program: Agreements with the individual states will run for 18 months with a provision for an automatic, one-time 12-month renewal. In order to qualify for the renewal, both parties must certify to the RRB Data Integrity Board, three months prior to the expiration of the agreement that:

(1) The program will continue to be conducted without change, and

(2) Each party certifies to the board in writing that the program has been conducted in compliance with the agreement.

The number of matches conducted with each state during the period of the match will vary from state to state, ranging from 2 to 4 depending on whether the agreement provides for matches to be conducted quarterly or every six months.

Procedure: The state agency will provide the RRB with a file of records. The data elements will consist of beneficiary identifying information, such as the name and Social Security Number (SSN), date of birth, and RRB Claim Number, if known. The RRB will then conduct a match on the identifying information.

If the matching operation reveals that the individual who had received benefits under the Railroad Retirement Act also received benefits from the state for any days in the period, the RRB will notify the state agency and provide benefit payment and Medicare Entitlement data for those matched individuals. The state agency will then make adjustments, as necessary, as required by law or regulation for those matched records.

Other information: The notice we are giving here is in addition to any individual notice.

We will furnish a copy of this notice to both Houses of Congress and the Office of Management and Budget.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 2010-25974 Filed 10-14-10; 8:45 am]

BILLING CODE 7905-01-P

SMALL BUSINESS ADMINISTRATION

Audit and Financial Management Advisory Committee (AFMAC)

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Audit and Financial Management Advisory Committee (AFMAC). The meeting will be open to the public.

DATES: The meeting will be held on October 27, 2010 from 1 p.m. to approximately 4 p.m. Eastern Daylight Time.

ADDRESSES: The meeting will be held at the U.S. Small Business Administration, 409 3rd Street, SW., Office of the Chief Financial Officer Conference Room, 6th Floor, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), SBA announces the meeting of the AFMAC. The AFMAC is tasked with providing recommendation and advice regarding the Agency's financial management, including the financial reporting process, systems of internal controls, audit process, and process for monitoring compliance with relevant laws and regulations.

The purpose of the meeting is to discuss the SBA's Financial Reporting, Audit Findings to Date, FMFIA Assurance/A-123 Internal Control Program, Credit Modeling, Agency Financial Report, and Agency Performance Report.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public, however advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the AFMAC must contact Jonathan Carver, by fax or e-mail, in order to be placed on the agenda. Jonathan Carver, Chief Financial Officer, 409 3rd Street, SW., 6th Floor, Washington, DC 20416, phone: (202) 205-6449, fax: (202) 205-6969, e-mail: Jonathan.Carver@sba.gov.

Additionally, if you need accommodations because of a disability or require additional information, please contact Jeff Brown at (202) 205-6117, e-mail: Jeffrey.Brown@sba.gov, SBA, Office of Chief Financial Officer, 409 3rd Street, SW., Washington, DC 20416.

For more information, please visit our Web site at <http://www.sba.gov/aboutsba/sbaprograms/cfo/index.html>.

Dan S. Jones,

White House Liaison.

[FR Doc. 2010-26000 Filed 10-14-10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

In the Matter of: Camera Platforms International, Inc., Castleguard Energy, Inc., CD Warehouse, Inc., Ceatech USA, Inc., Cedyco Corp., Cell Robotics International, Inc., Cell Wireless Corp., Cellcom Corporation (n/k/a Cellcom I Corp.), and Central Utilities Production Corp.; Order of Suspension of Trading

October 13, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Camera Platforms International, Inc. because it has not filed any periodic reports since the period ended September 30, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Castleguard Energy, Inc. because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of CD Warehouse, Inc. because it has not filed any periodic reports since the period ended March 31, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Ceatech USA, Inc. because it has not filed any periodic reports since the period ended July 31, 2003.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cedyco Corp. because it has not filed any periodic reports since the period ended September 30, 1994.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cell Robotics International, Inc. because it has not filed any periodic reports since the period ended March 31, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information

concerning the securities of Cell Wireless Corp. because it has not filed any periodic reports since the period ended September 30, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cellcom Corporation (n/k/a Cellcom I Corp.) because it has not filed any periodic reports since the period ended December 31, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Central Utilities Production Corp. because it has not filed any periodic reports since the period ended June 30, 2002.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on October 13, 2010, through 11:59 p.m. EDT on October 26, 2010.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2010-26123 Filed 10-13-10; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63070; File No. SR-Phlx-2010-129]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Rebates and Fees for Adding and Removing Liquidity

October 8, 2010.

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 September 27, 2010, NASDAQ OMX PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rebates and Fees for Adding and Removing Liquidity in Select Symbols to amend its current fees for removing liquidity and also add certain fees to apply to Complex Orders.

While changes to the Exchange’s Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated this proposal to be effective for trades settling on or after October 1, 2010.

The text of the proposed rule change is available on the Exchange’s Web site at <http://www.nasdaqtrader.com/micro.aspx?id=PHLXfilings>, at the principal office of the Exchange, at the Commission’s Public Reference Room, and on the Commission’s Web site at <http://www.sec.gov>.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to incentivize Broker-Dealers that route Customer orders to use the Exchange’s enhanced automated opening system ³ as well as to route Complex Order volume to the Exchange. The increased Customer volume should benefit market makers ⁴ and other Broker-Dealers engaged in proprietary trading.

The Exchange is proposing to amend its current Rebates and Fees for Adding and Removing Liquidity in Select

³ See Exchange Rule 1017(l).

⁴ The Exchange market maker category includes Specialists (see Rule 1020) and Registered Options Traders (Rule 1014(b)(i) and (ii)), which includes Streaming Quote Traders or SQTs (see Rule 1014(b)(ii)(A)) and Remote Streaming Quote Traders or RSQTs (see Rule 1014(b)(ii)(B)).

Symbols to apply only to single contra-side orders, which will now be part A of Section I of the Fee Schedule. The Select Symbols currently listed on the Fee Schedule will remain the same.⁵ The Exchange is proposing to increase the Directed Participant and Specialist, ROT, SQT and RSQT Fee for Removing Liquidity to \$0.33 per contract. Currently, Directed Participants are assessed a \$0.30 per contract Fee for Removing Liquidity and Specialists,

ROTs, SQTs and RSQTs are assessed a \$0.32 per contract Fee for Removing Liquidity.

The Exchange is also proposing to add separate Rebates and Fees for Adding and Removing Liquidity in Select Symbols for the electronically executed Complex Order⁶ side of any transaction as a new part B of Section I of the Fee Schedule. The Exchange is proposing to pay a Rebate for Adding Liquidity and assess a Fee for Removing Liquidity,

which would apply only to the Complex Order side of a transaction. For example, one component of a Complex Order is a buy order that trades with a "simple" or non-Complex Order sell order, the sell order is subject to the fees in part A of Section I of the Fee Schedule and the buy order is subject to the fees in new part B of Section I of the Fee Schedule.

The proposed fees are as follows:

| | Customer | Directed participant | Specialist, ROT, SQT and RSQT | Firm | Broker-dealer | Professional |
|-----------------------------------|----------|----------------------|-------------------------------|--------|---------------|--------------|
| Rebate for Adding Liquidity | \$0.22 | \$0.25 | \$0.23 | \$0.10 | \$0.10 | \$0.20 |
| Fee for Removing Liquidity | 0.25 | 0.25 | 0.27 | 0.27 | 0.35 | 0.27 |

The Exchange also proposes to apply these fees above as follows:

- Customer Complex Orders would receive the Rebate for Adding Liquidity when those orders are electronically executed against a [sic]⁷ Customer contra-side order with the same Complex Order strategy.
- Customer Complex Orders that are executed against a Customer contra-side order with the same Complex Order strategy would not be assessed the Fee for Removing Liquidity.
- A Professional, Directed Participant, Firm, Broker-Dealer and Specialist, ROT, SQT and RSQT would be assessed the Fees for Removing Liquidity when those orders are executed against a contra-side order with the same Complex Order strategy.
- A single contra-side order that is executed against the individual components of a Complex Order would be assessed the fees in Part A of this Section.
- The individual components of a Complex Order would be assessed the fees in Part B of this Section.

The following would continue to apply to the fees designated as Parts A and B:

- The Monthly Cap on transaction fees that are currently applicable to ROTs and Specialists transacting equity options will not be applicable to the Select Symbols.
- The Firm Related Equity Option Cap will not be applicable to the Select Symbols.
- The Market Access Provider ("MAP") Subsidy will not apply to

electronic transactions in the Select Symbols.

- Payment for Order Flow fees will not be collected on transactions in the Select Symbols.
- The Options Floor Broker Subsidy will be applicable to qualifying transactions in the Select Symbols (*see* Options Floor Broker Subsidy Fees).
- The Cancellation Fee will continue to apply to the Select Symbols.
- Transactions in the Select Symbols executed via open outcry will be subject to the Equity Options Fees (*see* Equity Options Fees in Section II). However, if one side of the transaction is executed using the Options Floor Broker Management System and any other side of the trade was the result of an electronically submitted order or a quote, then these fees will apply to the FBMS contracts and contracts that are executed electronically on all sides of the transaction.

The Exchange is removing the following language, which previously related to Complex Orders for fees in Section I: "Regular Equity Option transaction fees will apply to Complex Orders that are electronically executed against a contra-side order with the same Complex Order Strategy." Also, the following language is proposed to be deleted: "Single contra-side orders that are executed against the individual components of Complex Orders will be charged according to the above fees. The individual components of such a Complex Order will be charged according to the above fees." Because Complex Orders are now part B of this

Fee Schedule, this language is no longer necessary.

The Exchange is proposing to amend the application of the Rebates and Fees for Adding and Removing Liquidity in Select Symbols, Section I, to its opening and auction processes by adopting new part C. Currently, Section I does not apply to contracts executed during the Exchange's opening process,⁸ except for the Firm and the Broker-Dealer Fee for Removing Liquidity. Also, currently, Customer, Professional, Directed Participant, and Specialist, ROT, SQT and RSQT Fees for Removing Liquidity do not apply to transactions resulting from electronic auctions.⁹ Firm and Broker-Dealer Fees for Removing Liquidity do apply to transactions resulting from electronic auctions. Customer, Professional, Directed Participant, and Specialist, ROT, SQT and RSQT Rebates for Adding Liquidity do not apply to transactions resulting from electronic auctions.

The Exchange is proposing to amend the fees that apply to all electronic auctions, including the Exchange's opening process. The Exchange proposes that a Customer would receive a Rebate for Adding Liquidity in an electronic auction and during the Exchange's opening process, except when such Customer order is contra to another Customer order. A Customer would not be assessed a Fee for Removing Liquidity in an electronic auction and during the Exchange's opening process. The Exchange also proposes that Professional, Directed

⁵ The Rebates and Fees for Adding and Removing Liquidity in Select Symbols will continue to apply only to electronic orders.

⁶ A complex order strategy means any Complex Order involving any option series which is priced at a net debit or credit (based on the relative prices of each component). The Exchange will calculate both a bid price and an offer price for each complex

order strategy based on the current PBBO (as defined below) for each component of the Complex Order and the bid/ask differential for each component. *See* Exchange Rule 1080, Commentary .08(a)(ii).

⁷ The Commission notes that the Exhibit 5 attached to the form 19b-4 states that "Customer Complex Orders will receive the Rebate for Adding

Liquidity when electronically executed against a non-Customer contra-side order with the same Complex Order Strategy." (Emphasis added).

⁸ *See* Exchange Rule 1017, Openings in Options.

⁹ Electronic auctions include, without limitation, the Complex Order Live Auction ("COLA"), and Quote and Market Exhaust auctions.

Participant, Firm, Broker-Dealer and Specialist, ROT, SQT and RSQT Fees for Removing Liquidity would apply to transactions resulting from electronic auctions and the Exchange's opening process.

While changes to the Exchange's Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated this proposal to be effective for trades settling on or after October 1, 2010.

2. Statutory Basis

The Exchange believes that its proposal to amend its schedule of fees is consistent with Section 6(b) of the Act¹⁰ in general, and furthers the objectives of Section 6(b)(4) of the Act¹¹ in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities. The Exchange's proposal to assess separate fees for Complex and non-Complex Orders in Section I of its Fee Schedule is consistent with industry fees that allow for different rates to be charged for different order types originated by dissimilarly classified market participants.¹² The Exchange believes that this amendment to the fees is both reasonable and equitable because the fees are within the range assessed other market participants and are similar to fees being assessed by the International Securities Exchange, LLC ("ISE") for complex order executions.¹³

The Exchange proposes to pay a Rebate for Adding Liquidity to Customers when such transaction is contra to a non-Customer order during an electronic auction and opening processes. Similarly, the Exchange proposes to not assess a fee to a Customer during such processes. The Exchange also proposes to apply the Fee for Removing Liquidity to all non-Customer market participants equally during electronic auction or opening processes. The Exchange believes that these proposals are both reasonable and equitable because they should incentivize Customer orders and attract additional order flow to the Exchange. Also, all other participants are equally assessed the applicable Fees for Removing Liquidity.

The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be

excessive. The Exchange believes that the fees it charges for options overlying the various Select Symbols remain competitive with fees charged by other venues and therefore continue to be reasonable and equitably allocated to those members that opt to direct orders to the Exchange rather than competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁴ 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 shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-Phlx-2010-129 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2010-129. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro/shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-Phlx-2010-129 and should be submitted on or before November 5, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Florence E. Harmon,
Deputy Secretary.

[FR Doc. 2010-25984 Filed 10-14-10; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63068; File No. SR-BYX-2010-001]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend BYX Rule 11.8, Entitled "Obligations of Market Makers"

October 8, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,²

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4).

¹² See Securities Exchange Act Release No. 62805 (August 31, 2010), 75 FR 54682 (September 8, 2010) (SR-ISE-2010-90).

¹³ See ISE's Schedule of Fees.

¹⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

notice is hereby given that on September 27, 2010, BATS Y-Exchange, Inc. ("BYX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend BYX Rule 11.8, which relates to the obligations of market makers registered with BYX ("Market Makers").

The text of the proposed rule change is available at the Exchange's Web site at <http://www.batstrading.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt rules to enhance minimum quotation requirements for market makers. Under the proposal, the Exchange will require market makers for each stock in which they are registered to continuously maintain a two-sided quotation within a designated percentage of the National Best Bid ("NBB") and National Best Offer ("NBO") (or, if there is no NBB or NBO, the last reported sale). These enhanced market maker quotation requirements are intended to eliminate trade executions against market maker placeholder quotations traditionally priced far away from the inside market, commonly known as "stub quotes." They are also intended to augment and work in relation to the single stock pause standards already in place on a

pilot basis for stocks in the S&P 500[®] Index,³ the Russell 1000[®] Index, as well as a pilot list of Exchange Traded Products.⁴

Under the proposal, the Exchange will require registered market makers to enter and maintain quotes priced at no more than a certain percentage away from the national inside bid and offer. Permissible quotes are determined by the individual character of the security, the time of day in which the quote is entered, and other factors which are summarized below.

For issues subject to an individual stock trading pause, a permissible quote is determined by first looking at the applicable individual stock pause trigger percentage of the security and then reducing that number by 2%. Since currently the individual stock pause trigger percentage utilized by the primary listing markets is 10%, a market maker's quote in a [sic] such a security may not be more than 8% away from the NBBO as appropriate. Once a compliant quote is entered, it may rest without adjustment until such time as it moves to within ½ of 1% of the applicable stock pause trigger percentage (*i.e.*, currently 9.5%) whereupon the market maker must immediately move its quote back to at least the permissible default level of 8% away from the NBBO. During times in which a stock pause trigger percentage is not applicable (*e.g.*, before 9:45 a.m. and after 3:35 p.m.), a market maker must maintain a quote no further than 20% away from the inside (*i.e.*, it may rest without adjustment until it reaches 21.5%). In the absence of a NBB or NBO, the above calculations will remain the same, but will use the national last sale instead of the absent bid or offer.

For securities not subject to any individual stock trading pause, the proposal will a [sic] assume a hypothetical 32% stock pause trigger percentage, apply a 2% reduction, and require market makers in those issues to maintain quotes no more than 30% away from the NBBO. Like securities subject to stock trading pauses, once a compliant quote is entered, it may rest without adjustment until such time as it moves to within ½ of 1% of its applicable pause trigger percentage (31.5%) whereupon the market maker

³ See, *e.g.*, Securities Exchange Act Release No. 62340 (June 21, 2010), 75 FR 36768 (June 28, 2010) (SR-BATS-2010-014). The Exchange is separately working to amend its rules prior to commencement of operations to make clear that it will pause trading in Circuit Breaker Securities when an individual stock trading pause is issued by a primary listing market.

⁴ See, *e.g.*, Securities Exchange Act Release No. 62884 (September 10, 2010), 75 FR 56618 (September 16, 2010) (SR-BATS-2010-018); *see id.*

must immediately move its quote back to at least the permissible default level of 30%. These requirements shall apply to Regulation NMS securities during normal market hours.

Nothing in the above precludes a market maker from voluntarily quoting at price levels that are closer to the NBBO than required under the proposal.

The Exchange proposes to offer optional functionality to Exchange Market Makers to assist such Market Makers with the quotation obligations proposed by this filing. Specifically, at 9 a.m. Eastern Time, the Exchange will extract information submitted by the Market Maker that provides specific quote instructions for the Exchange to enter a quote on the Market Maker's behalf consistent with proposed paragraph (d). The Exchange proposes to enter the initial bid and offer at the Designated Percentage and to cancel and replace the bid or offer if it drifts away from the NBBO to the Defined Limit or away from the Designated Percentage towards the NBBO by a number of percentage points determined by the Exchange. The Exchange will determine and publish this percentage in a circular distributed to Members from time to time; the Exchange wishes to retain this flexibility in the event it wishes to modify the number periodically in the future, for instance, to mitigate the amount of quotation information resulting from Exchange generated Market Maker quotes. If a bid or offer entered pursuant to proposed paragraph (e) is executed, the Exchange will re-enter a new bid or offer on behalf of a Market Maker. Bids and offers entered by the Exchange consistent with proposed paragraph (e) to replace a cancelled or executed quotation will be entered at the Designated Percentage away from the NBBO. Such orders will be posted by the Exchange as BATS Only Orders,⁵ and will be maintained on the Exchange during Regular Trading Hours⁶ unless cancelled by the Market Maker pursuant to the Exchange's Rules. In the event a Market Maker cancels the quotations entered by the Exchange in accordance with proposed paragraph (e), such Market Maker remains responsible for compliance with the requirements of paragraph (d).

In order to adopt the above-described market maker quotation obligations, the Exchange proposes to modify Rule 11.18(a)(1), which currently contains a two-sided quotation obligation, to cross-reference the above-described market maker quotation obligations in new

⁵ As defined in Rule 11.9(c)(4).

⁶ Defined in Rule 1.5(w) as 9:30 a.m. to 4:00 p.m. Eastern Time.

paragraph (d). In addition, because proposed paragraph (d) makes clear that the obligations of that paragraph apply during Regular Trading Hours, the Exchange proposes to delete paragraph (b) of current Rule 11.8 related to the [sic] when the current quoting obligations apply. Finally, the Exchange proposes deletion of current Rule 11.8(e), related to temporary withdrawal, because Exchange Rule 11.5(d) already provides a Market Maker with the ability to withdraw his or her status as a Market Maker and Rule 11.7(b) already provides a Market Maker with the ability to terminate his or her registration in a security. The Exchange believes that these mechanisms are sufficient for a Market Maker to withdraw or terminate its registration in a security or as a Market Maker without the need for an additional provision related to withdrawal.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.⁷ In particular, the proposed change is consistent with Section 6(b)(5) of the Act,⁸ because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest. The proposed rule change is also designed to support the principles of Section 11A(a)(1)⁹ of the Act in that it seeks to assure fair competition among brokers and dealers and among exchange markets. The Exchange believes that the proposed rule meets these requirements in that it promotes uniformity across markets concerning minimum market maker quotation requirements. The Exchange believes that the proposed optional functionality to assist Exchange Market Makers in maintaining continuous, two-sided limit orders in the securities in which they are registered will encourage Market Makers to remain registered with and trade on the Exchange, thus providing valuable liquidity to the Exchange; at the same time, the Exchange believes that the proposed functionality will keep Exchange generated quotations within reasonable reach of the NBBO and that the elimination of “stub quotes”

is important for the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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 e-mail to rule-comments@sec.gov. Please include File Number SR-BYX-2010-001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BYX-2010-001. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR-BYX-2010-001 and should be submitted on or before November 5, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Florence E. Harmon,
Deputy Secretary.

[FR Doc. 2010-25952 Filed 10-14-10; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-63067; File No. SR-NYSEArca-2010-78]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change Relating to Listing and Trading Shares of Jefferies Commodity Real Return ETF

October 8, 2010.

I. Introduction

On August 17, 2010, NYSE Arca, Inc. (“NYSE Arca” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade shares (“Shares”) of Jefferies Commodity Real Return ETF (the “Fund”). The proposed rule change was published for comment in the

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78k-1(a)(1).

¹⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Federal Register on September 3, 2010.³ The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to list and trade the Shares pursuant to NYSE Arca Equities Rule 8.200, Commentary .02, which governs the listing and trading of Trust Issuer Receipts (“TIRs”) that invest in “Financial Instruments.” The Exchange represents that the Shares satisfy the requirements of NYSE Arca Equities Rule 8.200, Commentary .02, and thereby qualify for listing on the Exchange.

As described in greater detail in the Notice, the Fund will invest substantially all of its assets in exchange-traded futures in commodities that comprise the Thomson Reuters/Jefferies CRB 3 Month Forward Index (“Index”), or in other derivatives. The Fund establishes long positions in futures contracts on the nineteen physical commodities that comprise the Index (“Index Commodities”) with the goal of tracking the changes, either positive or negative, to the Index over time. The Managing Owner of the Fund adjusts the Fund’s portfolio from time to time to conform to periodic changes in the identity and/or relative weighting of the Index Commodities.

The Exchange deems the Shares to be equity securities, which subjects trading in the Shares to the Exchange’s existing rules governing the trading of equity securities, and has represented that trading in the Shares on the Exchange will occur in accordance with NYSE Arca Equities Rule 8.200(e). The Exchange has also represented that it has appropriate rules to facilitate transactions in the Shares during all trading sessions.

Additional details regarding the Shares and the Fund including, among other things, the organization and structure of the Fund, the dissemination and availability of information about the Fund and the Index, trading halts, applicable trading rules, surveillance, and the Information Bulletin can be found in the Notice.⁴

III. Discussion and Commission’s Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to

a national securities exchange.⁵ In particular, the Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act,⁶ which requires, among other things, that the Exchange’s rules be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission notes that it has previously permitted the listing and trading of TIRs based on commodities indexes.⁷ In addition, the Shares will be listed and traded pursuant to Commentary .02 to NYSE Arca Equities Rule 8.200, and the Exchange represents that the Shares will conform to the existing initial and continued listing criteria under this rule.

In addition, the Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,⁸ which sets forth Congress’ finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities.

Quotation and last-sale information for the Shares will be disseminated through the facilities of the Consolidated Tape Association. The Intra-day Indicative Value (“IIV”) will be published by the Fund’s Index Calculation Agent every 15 seconds through one or more major market data vendors and on the Fund’s Managing Owner’s Web site. The Net Asset Value (“NAV”) of the Fund will be published by the Managing Owner of the Fund, and will be disseminated to all market participants at the same time. The Exchange has also noted that information regarding the closing prices and settlement prices of futures on the Index Commodities are readily available from Web sites of the applicable futures exchanges, automated quotation

systems, published or other public sources, or online information services such as Bloomberg or Reuters. The relevant futures exchanges also provide delayed futures information on current and past trading sessions and market news free of charge on their respective Web sites. Moreover, the Fund’s Web site (<http://www.jamfunds.com/jcis>) will also disseminate the Fund holdings on a daily basis.

The Exchange shall make available on its Web site daily trading volume of the Shares, closing prices of the Shares, and the corresponding NAV. In addition, the Fund’s website will provide the following information: (1) The current net asset value per share daily and the prior business day’s NAV and the reported closing price; (2) the mid-point of the bid-ask price in relation to the NAV as of the time the NAV is calculated; (3) a calculation of the premium or discount of such price against such NAV; (4) data in chart format displaying the frequency distribution of discounts and premiums of the Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters; (5) the Fund’s prospectus; and (6) other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Exchange has represented that the NAV for the Fund will be disseminated to all market participants at the same time. If the Exchange becomes aware that the NAV with respect to the Shares is not being disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. Furthermore, the Exchange has represented that it may halt trading during the day in which the interruption to the dissemination of the IIV, the Index or the value of the underlying futures occurs.

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading on the Exchange in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the underlying futures contracts; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair

³ See Securities Exchange Act Release No. 62768 (August 26, 2010), 75 FR 54199 (“Notice”).

⁴ See *supra* note 3.

⁵ In approving this proposed rule change, the Commission notes that it has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁶ 15 U.S.C. 78f(b)(5).

⁷ See Securities Exchange Act Release No. 58457 (September 3, 2008), 73 FR 52711 (September 10, 2008) (SR-NYSEArca-2008-91) (Listing of fourteen funds of the Currency and Commodity Trust pursuant to Rule 8.200, Commentary .02.)

⁸ 15 U.S.C. 78k-1(a)(1)(C)(iii).

and orderly market are present. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's "circuit breaker" rule or by the halt or suspension of trading in the underlying futures contracts.

In addition, NYSE Arca Equities Rule 8.200(e) sets forth certain requirements for ETP Holders acting as registered Market Makers in the Shares to facilitate surveillance.

In support of this proposal, the Exchange has made representations, including:

(1) The Fund will meet the initial and continued listing criteria under NYSE Arca Equities Rule 8.200, Commentary .02.

(2) The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable Federal securities laws.

(3) Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated IIV will not be calculated or publicly disseminated; (b) the procedures for purchases and redemptions of Shares in Baskets (including noting that Shares are not individually redeemable); (c) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (d) how information regarding the IIV is disseminated; (e) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

This approval order is based on the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act⁹ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,¹⁰ that the proposed rule change (SR-NYSEArca-2010-78), be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010-25949 Filed 10-14-10; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 7211]

In the Matter of the Review of the Designation of the Armed Islamic Group and All Associated Aliases as Foreign Terrorist Organizations Pursuant to Section 219 of the Immigration and Nationality Act, as Amended

Based upon a review of the Administrative Record assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the 2003 re-designation of the Armed Islamic Group (GIA) as foreign terrorist organization have changed in such a manner as to warrant revocation of the designation. Although the GIA no longer meets the criteria for designation as a foreign terrorist organization, its remnants and some senior leaders have joined al Qa'ida in the Islamic Maghreb (AQIM), a designated Foreign Terrorist Organization.

Therefore, I hereby determine that the designation of the Armed Islamic Group as a foreign terrorist organization, pursuant to Section 219 of the Immigration and Nationality Act, as amended (8 U.S.C. 1189), shall be revoked.

This determination shall be published in the **Federal Register**.

Dated: September 28, 2010.

Hillary Rodham Clinton,

Secretary of State.

[FR Doc. 2010-26082 Filed 10-14-10; 8:45 am]

BILLING CODE 4710-10-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35413]

Lancaster & Chester Railroad, LLC—Acquisition and Operation Exemption—Line of Lancaster & Chester Railway Company

Lancaster & Chester Railroad, LLC (L&C Railroad), a noncarrier, has filed a verified notice of exemption under 49

CFR 1150.31 to acquire and operate approximately 62 miles of rail line owned by Class III rail carrier Lancaster & Chester Railway Company as follows: (1) Approximately 29 miles of rail line from Chester, S.C. (milepost 0.0) to Lancaster, S.C. (milepost 29.0), plus approximately 2 miles of connecting track from milepost 5.0 in Chester County, S.C., to the connection with Consolidated Rail Corporation at former Survey Station 0+06 (milepost SG-346+2210) of the Seaboard Coast Line Railroad Company in Chester County; and (2) approximately 31 miles of rail line from Kershaw, S.C. (milepost SB-58.7) to Catawba, S.C. (milepost SB-89.5) including, for each of the lines, related rail property and trackage.

Because L&C Railroad's projected annual revenues will exceed \$5 million, L&C Railroad certified to the Board on August 30, 2010, that it had complied with the requirements of 49 CFR 1150.32(e) providing for notice to employees and their labor unions on the affected line. L&C Railroad also certified that its projected revenues as a result of this transaction will not exceed those that would qualify it as a Class III carrier.

This transaction is related to a concurrently filed verified notice of exemption in Docket No. FD 35414, *Gulf & Ohio Railways Holding Co., Inc., H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—Lancaster & Chester Railroad, LLC*, wherein the above parties seek to continue in control of L&C Railroad, upon L&C Railroad's becoming a Class III rail carrier.

The transaction may be consummated on or after October 31, 2010 (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 October 22, 2010 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35413, 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 Troy W. Garris, 2904 Corporate Cir., Flower Mound, TX. 75028.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: October 7, 2010.

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78s(b)(2).

¹¹ 17 CFR 200.30-3(a)(12).

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2010-25939 Filed 10-14-10; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35414]

Gulf & Ohio Railways Holding Co., Inc., H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—Lancaster & Chester Railroad, LLC

Gulf & Ohio Railways Holding Co., Inc. (G&O), H. Peter Claussen and Linda C. Claussen (the Claussens), noncarriers, have filed a verified notice of exemption to continue in control of Lancaster & Chester Railroad, LLC (L&C Railroad) upon L&C Railroad's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in Docket No. FD 35413, *Lancaster & Chester Railroad, LLC—Acquisition and Operation Exemption—Line of Lancaster & Chester Railway Company*. In that proceeding, L&C Railroad seeks an exemption under 49 CFR 1150.31 to acquire and operate approximately 62 miles of rail line owned by Lancaster & Chester Railway Company between (1) Chester and Lancaster, S.C., and (2) Kershaw and Catawba, S.C.

The transaction may be consummated on or after October 31, 2010 (the effective date of the exemption).

The Claussens own a controlling share of voting stock of G&O. G&O, in turn, wholly owns the following Class III rail carriers: (a) Conecuh Valley Railroad Co., Inc., which operates in Alabama; (b) Knoxville & Holston River Railroad Co., Inc., which operates in east Tennessee; (c) Laurinburg & Southern Railroad Co., Inc., which operates in North Carolina; (d) Piedmont & Atlantic Railroad, Inc., which operates in northwestern North Carolina under the trade name of Yadkin Valley Railroad; (e) Rocky Mount & Western Railroad Co., Inc., which operates in central North Carolina under the trade name of Nash County Railroad; (f) Three Notch Railroad Co., Inc., which operates in Alabama; and (g) Wiregrass Central Railroad Company, Inc., which operates in southeast Alabama.

The parties represent that: (1) The rail lines to be acquired by L&C Railroad do not connect with any other railroad in

the corporate family; (2) the transaction is not part of a series of anticipated transactions that would connect the rail lines with any other railroad in the corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. See 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

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. Stay petitions must be filed no later than October 22, 2010 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35414, 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 Troy W. Garris, 2904 Corporate Cir., Flower Mound, Tex. 75028.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: October 7, 2010.

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2010-25937 Filed 10-14-10; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Cameron County, TX

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Rescind Notice of Intent (NOI) to prepare an EIS.

SUMMARY: FHWA is issuing this notice to advise the public that the NOI to prepare an environmental impact

statement (EIS) for proposed improvements to United States Highway 181/State Highway 286 (Crosstown Expressway), in Nueces County, Texas, is being rescinded.

FOR FURTHER INFORMATION CONTACT:

Gregory S. Punske, P.E. District Engineer, Federal Highway Administration, Texas Division, 300 East 8th Street, Room 826, Austin, Texas 78701, Telephone (512) 536-5960.

SUPPLEMENTARY INFORMATION: On April 6, 2007, TxDOT and FHWA announced their revised Notice of Intent to prepare an EIS pursuant to 40 CFR 1508.22 and 43 TAC Sec. 2.5(e)(2) for a proposal to replace the existing US 181 Harbor Bridge and construct improvements to SH 286, in Nueces County, Texas. The project limits were defined as the limits of the schematic design. The project limits were as follows: the northern limit was the US 181 and Beach Avenue interchange located north of the Corpus Christi Ship Channel but south of the Nueces Bay Causeway; the southern limit was the SH 286 and SH 358 (South Padre Island Drive) interchange; the eastern limit was the Interstate Highway (IH) 37/US 181 intersection with Shoreline Boulevard; and the western limit was the IH 37 and Nueces Bay Boulevard interchange. The project limits totaled approximately 7.5 miles in length from north to south along US 181 and SH 286, and 2.1 miles in length from east to west along IH 37. The study limits were defined as the limits of potential impacts from the proposed action. The study limits were as follows: the northern limit was the US 181 and SH 35 interchange just south of Gregory; the southern limit was the SH 286 and SH 358 (South Padre Island Drive) interchange; the eastern limit was Shoreline Boulevard; and the western limit was the IH 37 and SH 358 (North Padre Island Drive) interchange. The EIS was in the preliminary stages of development. Scoping meetings were held for representatives from various cooperating agencies and for the public. The scoping meeting for the representatives from various cooperating agencies was held May 17, 2007, at the TxDOT Corpus Christi District Office in Corpus Christi, Texas. The scoping meeting for the public was held May 17, 2007, at the Oveal Williams Senior Activity Center in Corpus Christi, Texas.

FHWA and TxDOT have decided to rescind the revised Notice of Intent because of changes in the scope (managed toll lanes) and limits. We intend to publish a new NOI in the future, which will describe the new project scope and limits. The review of

the project under the new NOI will also comply with the requirements of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) Section 6002 environmental review process. All 6002 procedures for the proposed project will be followed in the future as the project proceeds with a new scope and limits. Comments or questions concerning the rescission of this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning, and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: October 7, 2010.

Gregory S. Punske,

District Engineer, Austin, Texas.

[FR Doc. 2010-25972 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

International Standards on the Transport of Dangerous Goods; Public Meeting

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice is to advise interested persons that PHMSA will conduct a public meeting in preparation for the 38th session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCOE TDG) to be held November 29–December 7, 2010, in Geneva, Switzerland. During this meeting, PHMSA is also soliciting comments relative to potential new work items which may be considered for inclusion in its international agenda.

Information Regarding the UNSCOE TDG Meeting

DATES: Wednesday, November 17, 2010; 1 p.m.–3:30 p.m.

ADDRESSES: The meeting will be held at the DOT Headquarters, West Building, Conference Rooms 8, 9 and 10, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Notification: Any person wishing to participate in the public meeting should send an e-mail to michael.stevens@dot.gov and include

their name and contact information (Organization/Address/Telephone Number) no later than November 10, 2010. Providing this information will facilitate the security screening process for entry into the building on the day of the meeting.

Conference Call Capability/Live Meeting Information: Conference call-in and “live meeting” capability will be provided for this meeting. Specific information on call-in and live meeting access will be posted when available at <http://www.phmsa.dot.gov/hazmat/regs/international>.

FOR FURTHER INFORMATION CONTACT: Mr. Duane Pfund, Acting Director, Office of Hazardous Materials Technology or Mr. Shane Kelley, International Transportation Specialist, Office of Hazardous Materials Safety, Department of Transportation, Washington, DC 20590; (202) 366-0656.

SUPPLEMENTARY INFORMATION: The primary purpose of this meeting will be to prepare for the 38th session of the UNSCOE TDG. The 38th session of the UNSCOE TDG is the last of four meetings scheduled for the current 2009–2010 biennium. The UNSCOE will consider proposals for the 17th Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations which will come into force in the international regulations from January 1, 2013. Topics on the agenda for the UNSCOE TDG meeting include:

- Recommendations made by the Sub-Committee at previous sessions.
- Explosives and related matters.
- Listing, classification and packing.
- Electric storage systems.
- Electronic data interchange (EDI) for documentation purposes.
- Cooperation with the International Atomic Energy Agency (IAEA).
- Global harmonization of transport of dangerous goods regulations.
- Guiding principles for the Model Regulations.
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- Program of work for the biennium 2011–2012.

In addition, PHMSA is soliciting comments on how to further enhance harmonization for international transport of hazardous materials. PHMSA has finalized a broad international strategic plan and welcomes input on items which stakeholders believe should be included as specific initiatives within this plan. PHMSA's Office of International Standards Strategic Plan can be accessed at: <http://www.phmsa.dot.gov/hazmat/regs/international>.

The public is invited to attend without prior notification. Due to the heightened security measures participants are encouraged to arrive early to allow time for security checks necessary to obtain access to the building. Following the 38th session of the UNSCOE TDG, PHMSA will place a copy of the Sub-Committee's report and a summary of the results on PHMSA's Hazardous Materials Safety Homepage at <http://www.phmsa.dot.gov/hazmat/regs/international>.

Documents

Copies of documents for the UNSCOE TDG meeting and the meeting agenda may be obtained by downloading them from the United Nations Transport Division's Web site at: <http://www.unece.org/trans/main/dgdb/dgsubc/c32010.html>. PHMSA's site at <http://www.phmsa.dot.gov/hazmat/regs/international> also provides additional information regarding the UNSCOE TDG and related matters such as summaries of decisions taken at previous sessions of the UNSCOE TDG.

Issued in Washington, DC, on October 6, 2010.

Magdy El-Sibaie,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 2010-25913 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Seventh Meeting—Special Committee 222: Inmarsat Aeronautical Mobile Satellite (Route) Services

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 222: Inmarsat Aeronautical Mobile Satellite (Route) Services meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 222: Inmarsat Aeronautical Mobile Satellite (Route) Services.

DATES: The meeting will be held November 3–5, 2010, Wednesday, November 3, 2010 from 1:30 p.m.–4:30 p.m., Thursday, November 4, 9 a.m.–4:30 p.m., and Friday, November 5, 9–11:30 a.m.. Note that this meeting will conclude on Thursday if all the business has been concluded.

ADDRESSES: The meeting will be held at RTCA Headquarters, 1828 L. Street, NW., Suite 805, Washington, DC, 20036.
Dress: Business Casual.

FOR FURTHER INFORMATION CONTACT: RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC, 20036; telephone (202) 833-9339; fax (202) 833-9434; Web site <http://www.rtca.org>.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 222: Inmarsat Aeronautical Mobile Satellite (Route) Services. The agenda will include:

Agenda

- Opening Plenary (Introductions and Opening Remarks).
- Review and Approval of SC-222/WP-051, Summary for the 6th Meeting of Special Committee 222 held at ARINC on August 3, 2010.
 - Review and Approval of the Agenda for the 7th Meeting of SC-222, WP-053 (this document).
 - Old Business.
 - Review of/reports for the currently active Action Items regarding SBB Safety issues per the minutes of the 6th Plenary Meeting.
 - Release MASPS in Mid-August.
 - Create a summary table for interference from ATCt.
 - Confirm date and location for a November meeting of SC-222.
 - Working Papers and Discussions regarding SC-222 issues.
 - Status of ATCt filter development activities with ARINC AEEC discussions on this issue.
 - Discussion on new SBB documentation approach as presented in WP-047 at August meeting.
 - Status of LightSquared ATCt development and deployment.
 - Review, comment, discuss draft WP-052 DO-3xx SBB Safety Draft 1 (This action is expected to take most of Wednesday and Thursday).
 - Review, comment, discuss draft of Appendix B, ATCt Interface Model.
 - Additional working papers as may be provided in advance of the meeting.
 - Additional working papers as may be provided at the meeting.
 - Other Business.
 - FAA request for information concerning spectrum usage.
 - Revision to Terms of Reference, if necessary after Agenda Item 5b.
 - Review of Assignments and Action Items.
 - Date and Location for the 8th Meeting of SC-222.
 - Adjourn (no later than 11:30 a.m. Friday).

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral

statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on October 6, 2010.

Robert L. Bostiga,
RTCA Advisory Committee.

[FR Doc. 2010-25981 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance from certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Utah Transit Authority

[Supplement to Waiver Docket Number FRA-1999-6253]

As a supplement to the Utah Transit Authority's (UTA) petition for approval of shared use and waiver of certain FRA regulations (the original shared use waiver was granted by the FRA Railroad Safety Board on August 19, 1999, for the Sandy/Salt Lake TRAX Light Rail Transit line), UTA is amending the terms and conditions of the original waiver by constructing the Mid-Jordan LRT line extension of the current Sandy/Salt Lake TRAX LRT line. This extension will be urban rapid transit light rail, featuring some temporally separated shared trackage operation with the Bingham Branch of the General Railroad System.

The Bingham Branch has two short line freight railroads; the Savage Bingham & Garfield Railroad Company and the Utah Railway Company. UTA respectfully requests an additional 5-year extension of the current waiver, and a modification of the current waiver to include the Mid-Jordan extension and its new fleet of Siemens S70 TRAX vehicles. UTA submits that the extension and modifications of the waiver sought herein are in the public interest and consistent with railroad safety because UTA will adopt specific policies and procedures that will

provide a level of safety equivalent to that provided by full compliance with FRA regulations. UTA submits that this request is consistent with the waiver process for shared use. *See Statement of Agency Policy Concerning Jurisdiction Over the Safety of Railroad Passenger Operations and Waivers Related to Shared Use of the Tracks of the General Railroad System by Light Rail and Conventional Equipment, 65 FR 42529 (July 10, 2000); see also Joint Statement of Agency Policy Concerning Shared Use of the Tracks of the General Railroad System by Conventional Railroads and Light Rail Transit Systems, 65 FR 42626 (July 10, 2000).*

On August 19, 1999, UTA filed a petition for approval of shared use and waiver of certain FRA regulations pursuant to 49 CFR 211.7 for the Sandy/Salt Lake TRAX Light Rail Transit line. FRA granted the waiver for a period of 5 years until December 13, 2004. On August 12, 2004, UTA filed a petition requesting a 10-year extension of the waiver, and to additionally cover twenty-nine vehicles purchased from the Santa Clara Valley Transportation Authority (VTA). On December 20, 2004, FRA granted an extension of the waiver, including the VTA vehicles, for a period of 1 year, effective through December 13, 2005. On June 3, 2005, UTA filed a petition requesting a 5-year extension of the waiver. On December 15, 2005, FRA granted an extension of the waiver for a period of 5 years, effective through December 15, 2010.

UTA is expanding its original Sandy/Salt Lake TRAX LRT line by building the 10.6-mile Mid-Jordan LRT line extension, with temporally separated light rail and freight operations sharing track on the Bingham Branch. As part of this Mid-Jordan extension, UTA will reconstruct this existing Bingham Branch Track and add a new parallel track. This construction will allow that portion of the Mid-Jordan LRT line that runs on the Bingham Branch to utilize two tracks for light rail operations during the temporally separated passenger period from 5am-midnight daily, and all day Saturday and Sunday, with maximum authorized speed of 65 mph. Lastly, UTA will buy a new fleet of Siemens S70 TRAX vehicles that will operate throughout the entire light rail system. In addition to the TRAX vehicles for which UTA has already received a waiver of certain FRA regulations (existing TRAX vehicles), UTA intends to add seventy-seven Siemens S70 light-rail vehicles to its fleet. The S70 vehicles are very similar in nature to the existing TRAX vehicles, with minor differences.

UTA operates light rail vehicles that meet the equipment standards of the California Public Utilities Commission, General Order 143-B. The risk of collision between TRAX light rail vehicles will be minimized because movement of TRAX vehicles currently is controlled by UTA controllers in accordance with established operating rules. For this new extension, the same procedures will be in place. Specifically, UTA seeks a waiver from certain portions of 49 CFR, particularly §§ 219 Control of Alcohol and Drug Use; 221 Rear End Marking Devices; 222 Use of Locomotive Horns at Public Highway-Rail Grade crossings; 223 Safety Glazing Standards; 225 Railroad Accidents/ Incidents; 228 Hours of Service of Railroad Employees; 229 Locomotive Safety Standards; 231 Railroad Safety Appliance Standards; 234 Grade Crossing Signal Systems Safety; 238 Passenger Equipment Safety Standards; 239 Passenger Rail Emergency Preparedness; and 240 Qualification and Certification of Locomotive Engineers.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA-1999-6253) and may be submitted by any of the following methods:

- *Web site:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12-140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.-5 p.m.) at the above facility. All documents in the public docket are also available for

inspection and copying on the Internet at the docket facility's Web site at <http://www.regulations.gov>.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, 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) or at <http://www.dot.gov/privacy.html>.

Issued in Washington, DC, on October 8, 2010.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2010-26012 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2010-0328]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemption from the diabetes mellitus standard; request for comments.

SUMMARY: FMCSA announces receipt of applications from 27 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before November 15, 2010.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2010-0328 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200

New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf>.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year

period. The 27 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

Qualifications of Applicants

Juan C. Araoz Cespedes

Mr. Araoz Cespedes, age 50, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Araoz Cespedes meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Virginia.

William V. Barbrie

Mr. Barbrie, 52, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Barbrie meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class 10 operator's license from Rhode Island, which allows him to operate any motor vehicle except a motorcycle and a vehicle that weighs more than 26,000 pounds, carries 16 or more passengers or transports placarded amounts of hazardous materials.

Kerry W. Blackwell

Mr. Blackwell, 40, has had ITDM since 2003. His endocrinologist examined him in 2010 and certified that

he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Blackwell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A Commercial Driver's License (CDL) from Texas.

Mark S. Braddom

Mr. Braddom, 57, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Braddom meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Tennessee.

Mike G. Brambila

Mr. Brambila, 55, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Brambila meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Arizona.

Matthew T. Brown

Mr. Brown, 31, has had ITDM since age 1991. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions

resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Florida.

Richard G. Bruehl

Mr. Bruehl, 64, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Bruehl meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from Pennsylvania.

John P. Catalano

Mr. Catalano, 44, has had ITDM since 1975. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Catalano currently has a federal exemption to the vision standard, 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from New Jersey.

Travis A. Chandler

Mr. Chandler, 23, has had ITDM since 1999. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the

assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Chandler meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from Georgia.

Christopher G. Chegas

Mr. Chegas, 28, has had ITDM since 1994. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Chegas meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class C operator's license from Pennsylvania.

Gary J. Dionne

Mr. Dionne, 42, has had ITDM since 2003. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Dionne meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Idaho.

Thomas C. Donahue

Mr. Donahue, 58, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function

that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Donahue meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Massachusetts.

Joseph G. Greatens

Mr. Greatens, 63, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Greatens meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Wisconsin.

Marlin K. Johnson

Mr. Johnson, 70, has had ITDM since 2007. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

George Long, Jr.

Mr. Long, 71, has had ITDM since 1995. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in

the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Long meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from New Mexico.

Cary C. McAlister

Mr. McAlister, 39, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. McAlister meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Tennessee.

Dennis P. Miller

Mr. Miller, 53, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Miller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Robert F. Minacapelli

Mr. Minacapelli, 39, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more)

severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Minacapelli meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2009 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

Joe E. L. Radabaugh

Mr. Radabaugh, 51, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely.

Mr. Radabaugh meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Raul F. Sanchez

Mr. Sanchez, 56, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Sanchez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Texas.

Enrique E. Santiago

Mr. Santiago, 51, has had ITDM since 2007. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in

the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Santiago meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Florida.

Thomas A. Schmitt

Mr. Schmitt, 57, has had ITDM since 2009. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Schmitt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Iowa.

Leo A. Schmitz

Mr. Schmitz, 67, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Schmitz meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Ben D. Shelton, Jr.

Mr. Shelton, 41, has had ITDM since 2010. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin;

and is able to drive a CMV safely. Mr. Shelton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from Illinois.

Marlon J. Vanderheiden

Mr. Vanderheiden, 31, has had ITDM since 1989. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Vanderheiden meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Nestor P. Vargas, Jr.

Mr. Vargas, 43, has had ITDM since 1992. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Vargas meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds an operator's license from Washington.

Harold A. Wendt

Mr. Wendt, 75, has had ITDM since 2005. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years; understands diabetes management and monitoring; has stable control of his diabetes using insulin; and is able to drive a CMV safely. Mr. Wendt meets the requirements of the

vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).¹ The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary. The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

¹ Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

Issued on: October 8, 2010.

Larry W. Minor,

Associate Administrator, Office of Policy and Program Development.

[FR Doc. 2010-26056 Filed 10-14-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Request for Public Comment, Morgantown Municipal Airport, Morgantown, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The Federal Aviation Administration is requesting public comment on the proposed release of 46.53 acres of land currently owned by the City of Morgantown, Sponsor for the Morgantown Municipal Airport, Morgantown, West Virginia. The parcel is located within the Sixth Ward District of the City of Morgantown, Morgantown, West Virginia. The site is a 47.00 acre portion of the larger Morgantown Municipal Airport property. The land is currently being used as a cross wind runway. It has been determined that this runway is no longer needed for safety or capacity. The property is not a vital part of, or necessary for the Sponsor's operation and development of the Morgantown Airport. Once released, the land will change to a non-aeronautical use and will be transferred to the West Virginia Army National Guard ("AR-WVARNG"). Thereafter, AR-WVARNG will construct or cause the construction of and operate a West Virginia Army National Guard Readiness Center on the property. The development of this property will also bring the construction of a roadway and utilities that will be needed for subsequent development of aviation facilities on a part of the airport that is now remote and without utilities or access. The airport land being released is not needed for airport development as shown on the Airport Layout Plan. Fair Market Value has been determined based upon an appraisal of the Property.

DATES: Comments must be received on or before November 15, 2010.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Connie Boley-Lilly, Program Specialist, Federal Aviation Administration, Beckley Airports Field Office, 176 Airport Circle, Room 101, Beaver, West Virginia 25813.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Dan Boroff, City Manager of the City of Morgantown, Sponsor of Morgantown Municipal Airport at the following address: Dan Boroff, City Manager, City of Morgantown, Sponsor for Morgantown Municipal Airport, 389 Spruce Street, Morgantown, West Virginia 26505.

FOR FURTHER INFORMATION CONTACT:

Connie Boley-Lilly, Program Specialist, Beckley Airport Field Office, (304) 252-6216 ext. 125, FAX (304) 253-8028.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to release property at the Morgantown Municipal Airport, Morgantown, WV. Under the provisions of AIR 21 (49 U.S.C. 47108 (h)(2)).

The Morgantown Municipal Airport is proposing the release of approximately 46.53 acres of fee simple release to accommodate the construction of a West Virginia Army National Guard Readiness Center on the property. The crosswind runway, currently occupying the property, has been determined to be no longer need for safety and capacity at the airport. The release and sale of this property will allow the Sponsor to develop the roadway and utilities which will benefit this property, the hangar site, and the landside development site. This release will enhance the development of private aviation and commercial development of the east side of the airport.

Issued in Beckley, West Virginia, on October 1, 2010.

Matthew P. DiGiulian,

Manager, Beckley Airport Field Office, Eastern Region.

[FR Doc. 2010-25980 Filed 10-14-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35395]

Norfolk Southern Railway Company— Trackage Rights Exemption—Illinois Central Railroad Company

Pursuant to a written trackage rights agreement dated August 17, 2010, Illinois Central Railroad Company (IC) has agreed to grant overhead trackage rights to Norfolk Southern Railroad Company (NSR) over approximately 199.1 miles of rail line controlled by IC,¹ between: (1) Milepost 6.2 at Church,

¹ In a supplemental pleading filed October 6, 2010, NSR states that the portion of the involved

Ill., and milepost 70.0 at DuQuoin, Ill.; (2) milepost 71.0 at Eldorado Junction, Ill., and milepost 100.0 at Akin Junction, Ill.;² (3) milepost 62.9 at Akin Junction and milepost 40.7 at North Siding, Ill.; and (4) milepost 40.7 at North Siding and the IC's connection to the Western Tennessee Railroad at milepost 269.4 near Fulton, KY.³

The transaction may be consummated on or after October 29, 2010, the effective date of the exemption (30 days after the exemption is filed). The primary purpose of the trackage rights agreement is to enable NSR to route traffic over IC's rail lines for transportation beyond the endpoints of Church and the Western Tennessee Railroad connection.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Railway—Trackage Rights—Burlington Northern, Inc.*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease and Operate—California Western Railroad*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). 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. Stay petitions must be filed by October 22, 2010 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35395, 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 Daniel G. Kruger, Attorney, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510.

Board decisions and notices are available on our Web site at <http://www.stb.dot.gov>.

Decided: October 12, 2010.

route is over tracks owned by Paducah & Illinois Railroad Company (P&I) and that NSR's use of that portion of the involved trackage rights is contingent upon NSR obtaining a separate agreement to operate over P&I's trackage. In the event that NSR obtains such an agreement, NSR states that it will file a notice of exemption.

² NSR has existing trackage rights over IC's line between milepost 70.0 at DuQuoin and milepost 71.0 at Eldorado Junction.

³ A redacted, executed trackage rights agreement between IC and NSR was filed with the notice of exemption. Also, a motion for protective order was concurrently filed and will be addressed in a separate decision. On October 7, 2010, an unredacted version of the trackage rights agreement was filed under seal.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2010-26009 Filed 10-14-10; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF THE TREASURY

Departmental Offices; Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 2, § 10(a)(2), that a meeting will be held at the Hay-Adams Hotel, 16th Street and Pennsylvania Avenue, NW., Washington, DC, on November 2, 2010 at 10 a.m. of the following debt management advisory committee:

Treasury Borrowing Advisory Committee of The Securities Industry and Financial Markets Association.

The agenda for the meeting provides for a charge by the Secretary of the Treasury or his designate that the Committee discuss particular issues and conduct a working session. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. App. 2, § 10(d) and Public Law 103-202, § 202(c)(1)(B)(31 U.S.C. 3121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. App. 2, § 10(d) and vested in me by Treasury Department Order No. 101-05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103-202, 202(c)(1)(B).

Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B). In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 2, § 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the committee, premature disclosure of the committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

Treasury staff will provide a technical briefing to the press on the day before the committee meeting, following the release of a statement of economic conditions and financing estimates. This briefing will give the press an opportunity to ask questions about financing projections. The day after the committee meeting, Treasury will release the minutes of the meeting, any charts that were discussed at the meeting, and the committee's report to the Secretary.

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency official who may be contacted for additional information is Fred Pietrangeli, Deputy Director for Office of Debt Management, (202) 622-1876.

Dated: October 6, 2010.

Mary Miller,

Assistant Secretary (Financial Markets).

[FR Doc. 2010-25769 Filed 10-14-10; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8453-EX

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form

8453-EX, Excise Tax Declaration for an IRS e-file Return.

DATES: Written comments should be received on or before December 14, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, (202) 622-6665, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Excise Tax Declaration for an IRS e-file Return.

OMB Number: 1545-2082.

Form Number: Form 8453-EX.

Abstract: Form 8453-EX, Excise Tax Declaration for an IRS e-file Return, will be used in the Modernized e-File program. This form is necessary to enable the electronic filing of Forms 720, 2290, and 8849. The authority to e-file Form 2290 is Internal Revenue Code section 4481(e), as added by section 867(c) of Public Law 108-357.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Farms, Business or other for-profit institutions, Federal Government, Not-for-profit institutions, or State, Local or Tribal Government.

Estimated Number of Respondents: 15,000.

Estimated Time per Respondent: 2 hours 50 minutes.

Estimated Total Annual Burden Hours: 42,600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All

comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 8, 2010.

Allan Hopkins,
Tax Analyst.

[FR Doc. 2010-25944 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[IA-44-94]

Proposed Collection: Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, IA-44-94 (TD 8690), Deductibility, Substantiation, and Disclosure of Certain Charitable Contributions (§§ 1.170A-13(f) and 1.6115-1).

DATES: Written comments should be received on or before December 14, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be

directed to Allan Hopkins, at (202) 622-6665, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Deductibility, Substantiation, and Disclosure of Certain Charitable Contributions.

OMB Number: 1545-1464.

Regulation Project Number: IA-44-94.

Abstract: This regulation provides guidance regarding the allowance of certain charitable contribution deductions, the substantiation requirements for charitable contributions of \$250 or more, and the disclosure requirements for quid pro quo contributions in excess of \$75. The regulations affect donee organizations described in Internal Revenue code section 170(c) and individuals and entities that make payments to these organizations.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 1,750,000.

Estimated Time Per Respondent: 1 hour, 8 minutes.

Estimated Total Annual Burden Hours: 1,975,000.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of

information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 8, 2010.

Allan Hopkins,
Tax Analyst.

[FR Doc. 2010-25945 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-118620-97]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-118620-97 (TD 8855), Communications Excise Tax; Prepared Telephone Cards.

DATES: Written comments should be received on or before December 14, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Communications Excise Tax; Prepaid Telephone Cards.

OMB Number: 1545-1628.

Regulation Project Number: REG-118620-97.

Abstract: Carriers must keep certain information documenting their sales of prepaid telephone cards to other carriers to avoid responsibility for collecting tax. The regulations provide rules for the application of the communications excise tax to prepaid telephone cards.

Current Actions: There are no changes being made to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 104.

Estimated Time Per Respondent: 20 min.

Estimated Total Annual Burden Hours: 34.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 8, 2010.

Allan Hopkins,
Tax Analyst.

[FR Doc. 2010-25946 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-148867-03]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-148867-03, (TD 9327) Disclosure of Returns and Return Information in Connection with Written Contracts or Agreements for the Acquisition of Property or Services for Tax Administration Purposes.

DATES: Written comments should be received on or before December 14, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: REG-148867-03 (TD 9327) (Final) Disclosure of Returns and Return Information in Connection with Written Contracts or Agreements for the Acquisition of Property or Services for Tax Administration Purposes.

OMB Number: 1545-1821.

Regulation Project Number: REG-148867-03.

Abstract: The final regulations clarify that redisclosures or returns and return information by contractors to agents or subcontractors are permissible, and that the penalty provisions, written notification requirements, and safeguard requirements are applicable to these agents and subcontractors. Section 301.6103(n)-1(d) of the final regulations require that contractors, agents, and subcontractors who receive returns or

return information under the final regulations must provide written notice to their officers and employees of the purposes for which returns or return information may be used and of the potential civil and criminal penalties for unauthorized inspections or disclosures, including informing them of the imposition of punitive damages in the case of a willful inspection or disclosure or an inspection or disclosure which is the result of gross negligence. Section 301.6103(n)-1(e)(3) of the final regulations require that before the execution of a contract or agreement for the acquisition of property or services under which returns or return information will be disclosed, the contract or agreement must be made available to the IRS.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions and Federal, state, local or tribal governments.

Estimated Number of Respondents: 2,500.

Estimated Time per Respondent: 0.1 hr.

Estimated Total Annual Burden Hours: 250.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 8, 2010.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2010-25947 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notices 437, 437-A, 438 and 466

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Notices 437, 437-A, 438 and 466, Notice of Intention to Disclose.

DATES: Written comments should be received on or before December 14, 2010 to be assured of consideration.

ADDRESSES: Direct all written comments to Gerald Shields, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Notice of Intention to Disclose.
OMB Number: 1545-0633.

Notice Number: Notices 437, 437-A, 438, and 466.

Abstract: Section 6110(f) of the Internal Revenue Code requires that a notice of intention to disclose be sent to all persons to which a written determination (either a technical advice memorandum or a private letter ruling) is issued. That section also requires that such persons receive a notice if related

background file documents are requested. Notice 437 is issued to recipients of letter rulings; Notices 437-A to recipients of Chief Counsel Advice; Notice 438 to recipients of technical advice memorandums; and Notice 466 to recipients if a request for the related background file document is received. The notices also inform the recipients of their right to request further deletions to the public inspection version of written determinations or related background file documents.

Current Actions: There are no changes being made to the notice at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, not-for-profit institutions, farms, and State, local, or tribal governments.

Estimated Number of Respondents: 5,250.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 2,625.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 8, 2010.

Allan Hopkins,
Tax Analyst.

[FR Doc. 2010-25948 Filed 10-14-10; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Proposed Collection; Comment Request; Bank Secrecy Act Suspicious Activity Report Database Proposed Data Fields

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: FinCEN has begun the design of a new Bank Secrecy Act (BSA) database (the Database) and invites comment on the list of proposed data fields within the Database that will support Suspicious Activity Report (SAR) filings by financial institutions required to file such reports under the BSA. This notice does not propose any new regulatory requirements nor changes to the requirements related to suspicious activity reporting, but rather seeks input on technical matters as we transition from a system originally designed for collecting paper forms to a modernized IT environment for electronic reporting. The list of proposed data fields for the “BSA Suspicious Activity Report (BSA-SAR)” appears at the end of this notice. The proposed data fields reflect the filing requirement for all filers of SARs under the BSA. The SAR will be an e-filed dynamic and interactive report used by all BSA filing institutions to report suspicious activity to the Department of the Treasury. This request for comments covers 31 CFR 103.15, 31 CFR 103.16, 31 CFR 103.17, 31 CFR 103.18, 31 CFR 103.19, 31 CFR 103.20, and 31 CFR 103.21. This request for comments is being made pursuant to the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. 3506(c)(2)(A).

DATES: Written comments are welcome and must be received on or before December 14, 2010.

ADDRESSES: Written comments should be submitted to: Regulatory Policy and Programs Division, Financial Crimes Enforcement Network, Department of the Treasury, P.O. Box 39, Vienna, Virginia 22183, Attention: PRA Comments—BSA-SAR Database. BSA-SAR Comments also may be submitted by electronic mail to the following Internet address: regcomments@fincen.treas.gov, with the

caption, “Attention: BSA-SAR Database,” in the body of the text.

Inspection of comments. Comments may be inspected, between 10 a.m. and 4 p.m., in the FinCEN reading room in Vienna, VA. Persons wishing to inspect the comments submitted must request an appointment with the Disclosure Officer by telephoning (703) 905-5034 (not a toll-free call).

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Helpline at 800-949-2732, select option 7.

SUPPLEMENTARY INFORMATION:

Title: BSA Suspicious Activity Report by Financial Institutions. (See 31 CFR 103.15, 31 CFR 103.16, 31 CFR 103.17, 31 CFR 103.18, 31 CFR 103.19, 31 CFR 103.20, and 31 CFR 103.21).

OMB Number: 1506-XXXX.¹

Form Number: FinCEN Form 111.

Abstract: The statute generally referred to as the “Bank Secrecy Act,” Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, *inter alia*, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.² Regulations implementing Title II of the Bank Secrecy Act appear at 31 CFR Part 103. The authority of the Secretary to administer the Bank Secrecy Act has been delegated to the Director of FinCEN.

The Secretary of the Treasury was granted authority in 1992, with the enactment of 31 U.S.C. 5318(g), to require financial institutions to report suspicious transactions.

The information collected on the “report” is required to be provided pursuant to 31 U.S.C. 5318(g), as implemented by FinCEN regulations found at 31 CFR 103.15-21. The information collected under this requirement is made available to appropriate agencies and organizations as disclosed in FinCEN’s Privacy Act

System of Records Notice relating to SARs.³

Current Action: FinCEN is in the process of designing the Database to accept modernized electronic BSA reporting. The Database will accept XML-based dynamic, state-of-the-art reports. Batch and computer-to-computer filing processes will remain unchanged, although the file format will change to match the Database. Discrete filings will be based on Adobe *LiveCycle Designer ES* dynamic forms. All filings (discrete, batch, and computed-to-computer) will be accessed through the BSA E-Filing system⁴ using current registration and log-in procedures. During log-in of the discrete filing option, filers will be prompted through a series of questions⁵ (see BSA-SAR Comprehensive Summary of Proposed Data Fields, item 1 and Part III, at the end of this notice) to provide information that will identify the type of financial institution filing the SAR (depository institution, broker/dealer, casino, etc.). After log-in, the financial institution filing SARs through the discrete function will answer another set of questions consisting of a subset of the data field appropriate to the filer’s specific type of filing institution. Batch and computer-to-computer filers will file reports based on an electronic file specification that will be finalized after reviewing public comments received in response to this notice.

Dynamic forms are documents with a hierarchical structure that can be converted into XML. This structure can include structure from *XML Schema* and example XML files. Dynamic forms can be saved as PDF files or XDP files. XDP files are used by the *Adobe LiveCycle Form Server* to render files to PDF or HTML as needed. The report for the Database will be designed to be both dynamic (changing layout in response to data propagated from other sources) and interactive (capable of accepting user input). Currently, e-filed discrete forms are based on Designer 8.2.1. The dynamic features of these PDF forms can be manipulated by the Adobe Form Server during the rendering process, or

³ Treasury Department bureaus such as FinCEN renew their System of Records Notices every three years unless there is cause to amend them more frequently. FinCEN’s System of Records Notice for the SAR System was most recently published at 73 FR 42405, 42407-9 (July 21, 2008).

⁴ BSA E-Filing is a free service provided by FinCEN. More information on the filing methods may be accessed at <http://bsaeifiling.fincen.treas.gov/main.html>.

⁵ A series of predetermined questions will be used to establish the type of institution and filing in much the same manner as used in widely accepted income tax filing software.

¹ The SAR requirements are currently covered under the following OMB control numbers: 1506-0001 (SAR-DI), 1506-0006 (SAR-C), 1506-0015 (SAR-MSB), 1506-0019 (SAR-SF which includes broker-dealers, FCMs, IB-Cs, and Mutual Funds), and 1506-0029 (SAR-IC).

² Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the USA PATRIOT Act), Public Law 107-56.

by the Adobe Acrobat/ Acrobat Reader⁶ client during viewing. Dynamic forms allow *JavaScript* to be embedded, thereby enabling programmatic changes to the form layout as well as communication with various data sources (*SOAP*, *OLEDB*). Besides *JavaScript*, Adobe dynamic forms includes a proprietary scripting language called *FormCalc*, designed to be a simple language for users familiar with spreadsheet calculations.

The filing of the dynamic report will begin with the filer identifying the type of filing,⁷ followed by answering several questions about the filers' institution such as institution type (depository institution, broker-dealer, MSB, insurance, etc.), name of the institution, the institution's RSSD/EIN, and address.⁸ Responses to these questions will enable or "auto populate" certain data elements of the report with information obtained from third-party data sources, completing most of the filing institution's identifying information. The institution will then complete specific information on the subject(s) and nature of the suspicious activity, using the data elements appropriate to the type of financial institution filing. In case of a joint filed report, all data elements will be available for selection. In the event that a single filer requires access to additional elements not typical for the filer's type of financial institution, a "select all" feature will be available to enable all data elements for selection.

General Review of the BSA-SAR Comprehensive Summary of Proposed Data Fields⁹

Note: The following general comments apply to all filings, discrete, batch, and computer-to-computer. Critical fields are marked with an asterisk (*) and must be completed, if appropriate, by checking the "unknown" box.

- All filing institutions will complete item 1, "Type of Filing," once for each report.
- All filing institutions will complete Part I, "Subject Information," for each subject. Part I may be repeated as many times as necessary to cover all subjects. If item 2b is checked this Part may be left blank. Within Part I, subject contact

information, subject identification information, financial institution relationship information, and subject account information may be repeated as many times as necessary.

- All filing institutions must complete a Part II. Note that Part II items cover all filers. Filers are only required to complete those items that pertain to the report being made that apply to their institution. If a filer has additional information that would add value to the report, a "select all" feature will be available. Generally there will be one Part II per report. Unlimited entries in the "z other" sub category of instrument/product information, unlimited entries for instrument/product IDs and unlimited entries in the "z other" sub category of suspicious activity category and type will be available to electronic filers if needed.

- A Part III "Information Concerning Financial Institution Where Activity Occurred" is required for all reports. Part III may be repeated as many times as necessary to report an unlimited number of financial institutions and/or branches of financial institutions if necessary.

- A single Part IV "Filing Institution Contact Information" is required for each report.

- Part V "Suspicious Activity Information Narrative" is a text file that is limited to 17,000 characters (approximately six pages). Institutions filing electronically may, but are not required to, attach a MS Excel-compatible file (no larger than 1 MB) providing details in tabular form of transactions subject to the suspicious activity discussed in the text file.

Type of Review: Initial review of the proposed data elements of the Database in support of the electronic filing of a dynamic BSA-SAR.

Affected public: Business or other for-profit and not-for-profit financial institutions.

Frequency: As required.

Estimated Reporting Burden: Average of 60 minutes per report and 60 minutes recordkeeping per filing.¹⁰ (The reporting burden of the regulations 31 CFR 103.15, 31 CFR 103.16, 31 CFR 103.17, 31 CFR 103.18, 31 CFR 103.19, 31 CFR 103.20, and 31 CFR 103.21 is reflected in the burden for the form.)

Estimated Recordkeeping and Reporting Burden for 31 CFR 103.15, 31 CFR 103.16, 31 CFR 103.17, 31 CFR

103.18, 31 CFR 103.19, 31 CFR 103.20, and 31 CFR 103.21: 2 hours.¹¹

Estimated number of respondents = 83,455.

This includes depository institutions (27,262), broker-dealers (5,200), future commission merchants (143), insurance companies (1,200), introducing brokers in commodities (1602), money services businesses (37,977), and mutual funds (10,071). This number is equal to the total number of entities that are subject to filing SARs in fiscal year 2010. Given that the current proposal does not change the SAR filing requirement itself, FinCEN does not anticipate that the current proposal will change the number of entities subject to filing SARs.

Estimated Total Annual Responses = 1,281,225.

This number is equal to the total number of SARs filed by all filers in fiscal year 2010. Given that the current proposal does not change the SAR filing requirement itself, FinCEN does not anticipate that the current proposal will change the number of SARs being filed.

Estimated Total Annual Reporting and Recordkeeping Burden for Single Filer: 2,562,450 hours.

Joint filing:

In 2006, FinCEN expanded the broker-dealer (B-D), Future Commission Merchant (FCM), and Introducing Broker in Commodities (IB-C) filer option to file jointly to all filing entities. The intent of joint filing was the reduction of the number of actual reports filed. Due to significant database limitations and issues this expanded option was never formally put into practice. The advent of the FinCEN IT Modernization, the new database and the use of dynamic information collection tools as described above will now fully support joint filing by all BSA filers. In developing this concept, FinCEN is listing below a separate joint filing burden for review and comment. The numbers presented assume that the FY10 filings, as listed above, were all joint with one other filer which would result in a reduction of the number of reports filed by 50%. FinCEN realizes this reduced number to be overstated but elected to use it to establish a baseline for review.¹²

Estimated number of respondents = 83,455 (Note: no change from single filer option).

¹¹ Id.

¹² While the number of joint filers may increase from current levels due to the relative ease with which the Database can accommodate joint filing, this number is probably still a significant overestimate.

⁶ Adobe Acrobat Reader is free and can be downloaded from the Adobe Web site <http://www.adobe.com/reader>.

⁷ See item 1 of the BSA-SAR Comprehensive Summary of Proposed Data Fields at the end of this notice.

⁸ See Part III of the BSA-SAR Comprehensive Summary of Proposed Data Fields at the end of this notice.

⁹ The complete list of proposed data fields appears at the end of this notice.

¹⁰ The stated PRA burden is for a single institution filing. If the BSA-SAR report is filed jointly, an additional 30 minutes reporting time per joint filer is added to record the joint filer provided information and identification.

Estimated number of responses = 640,612 (See joint filing discussion above).

Estimated Total Annual Reporting and Recordkeeping Burden for Joint Filer: 1,601,530 hours

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the Bank Secrecy Act must be retained for five years.

Request for Comments:

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: October 8, 2010.

Charles M. Steele,

Deputy Director, Financial Crimes Enforcement Network.

BSA—SAR Comprehensive Summary of Proposed Data Fields

NOTE: Questions for which an answer must be provided ("critical fields") are identified with the * symbol in front of the data element number.

Type of Filing

- *1. Check all that apply:
 - a. Initial report
 - b. Correct/Amend prior report
 - c. Continuing activity report
 - d. Joint report
 - f. Prior report internal control/file number if items 1b or 1c are checked
 - g. DCN (*electronic view only*)

Part I: Subject Information

- 2. Check:
 - a. If entity
 - b. If all critical* subject information is unavailable
- *3. Individual's last name or entity's legal name
 - a. (check if) unknown

- *4. First name
 - a. (check if) unknown
- 5. Middle initial (middle name for electronic filers)
- Suffix (electronic view only)
- 5a. Gender
 - b. (Check if) Male
 - c. (Check if) Female
 - d. (Check if) Unknown
- 6. Alternate name, e.g. AKA—Individual or DBA—Entity (multiple entries allowed for electronic filers)
- 7. Occupation or type of business
 - a. NAICS Code
- *8. Address
 - a. (check if) unknown
- *9. City
 - a. (check if) unknown
- *10. State
 - a. (check if) unknown
 State should be derived through third party data as enhanced data if not provided and Country is US, Mexico or Canada and ZIP/Postal Code is provided
- *11. ZIP/Postal Code
 - a. (check if) unknown
 ZIP + 4 should be derived through third party data as enhanced data if not provided or verified through third party data if provided
- New Data Element of County—Derived through third party data as enhanced data
- New Data Elements for GEO Coding—Derived through third party data as enhanced data
- New Data Element of HIFCA code—Derived through third party data as enhanced data
- New Data Element of HIDTA code—Derived through third party data as enhanced data
- *12. Country Code
 - a. (check if) unknown
- *13. TIN (enter number in space provided and check appropriate type below)
 - a. (check if) unknown
- 14. TIN type (* if 13 is completed)
 - a. EIN
 - b. SSN—ITIN
 - c. Foreign
- *15. Form of identification for subject:
 - a. (check if) unknown (or not obtained)
 - b. (check if) Driver's license/state ID
 - c. (check if) Passport
 - d. (check if) Alien registration
 - e. Number
 - f. Issuing state
 - g. Country
 - z. (check if) Other (and specify type in space provided)
- *16. Date of birth mm/dd/yyyy
 - a. (check if) unknown
- 17. Phone number—type (multiple entries allowed for electronic filers)

- a. (check if) Home
- b. (check if) Work
- c. (check if) Mobile
- d. (check if) Fax
- 18. Phone number (multiple entries allowed for electronic filers)
 - a. Extension (if any)
- 19. E-mail address (if available) (multiple entries allowed for electronic filers)
- 19a. Web site (URL) address (if available) (multiple entries allowed for electronic filers)
- 20. Corroborative statement to filer?
 - a. (check if) Yes
 - b. (check if) No
- 21. Relationship of the subject to the filing institution (check all that apply)
 - a. Institution EIN (multiple related institution entries allowed for electronic filers)
 - b. Accountant
 - c. Agent
 - d. Appraiser
 - e. Attorney
 - f. Borrower
 - g. Customer
 - h. Director
 - i. Employee
 - j. Officer
 - k. Owner/Shareholder
 - l. No relationship to institution
 - z. Other (and specify type in space provided)
- 22. If item 21h, 21i, 21j, or 21k is checked, indicate status of relationship
 - a. (check if) Relationship continues
 - b. (check if) Terminated
 - c. (check if) Suspended/barred
 - d. (check if) Resigned
- 23. Action date if 22 b, c, or d is checked
- * 24. Financial Institution EIN and account number(s) affected that are related to subject, if any.
 - a. (check if) No known account involved
 - b. (check if) Non-US Financial Institution
 - c. EIN
 - d. account number
 - e. (check if) closed
 - f. account number
 - g. (check if) closed
 - h. EIN
 - i. account number
 - j. (check if) closed
 - k. account number
 - l. (check if) closed
 (paper filers have space to enter a second financial institution EIN and two more associated account numbers—items 24h through l; multiple financial institution and account number entries allowed for electronic filers)
- 25. Subject's role in suspicious activity (if applicable)

- a. (check if) Purchaser/Sender
 b. (check if) Payee/Receiver
 c. (check if) Both a & b
- Part II Suspicious Activity Information
- * 26. Amount involved in this report
 a. (check if) unknown
- * 27. Date or date range of suspicious activity for this report
 a. From: mm/dd/yyyy
 b. To: mm/dd/yyyy
28. Cumulative amount only if box 1c (continuing activity report) is checked
29. Were any of the following instrument/product type(s) involved in the suspicious activity? Check all that apply:
 a. Bank/cashier's check
 b. Bonds/Notes
 c. Commercial paper
 d. Credit card
 e. Debit card
 f. Foreign currency
 g. Forex transactions
 h. Funds transfer
 i. Futures/Options on futures
 j. Gaming instruments
 k. Government checks or EFT
 l. Hedge fund
 m. Insurance/annuity products
 n. Money orders
 o. Mortgage/Deed of Trust
 p. Mutual fund
 q. Options on securities
 r. Penny stocks/microcap securities
 s. Personal/Business check
 t. Prepaid access
 u. Security futures products
 v. Stocks
 w. Swap, hybrid or other derivative
 x. Travelers checks
 y. U.S. Currency
 z. Other (specify type in space provided) (multiple entries allowed)
30. Commodity type (if applicable)
31. Instrument description (if needed)
32. Market where traded (list of codes will be provided—dropdown menu for electronic filers)
33. IP Address (if available) (multiple entries allowed for electronic filers)
- 34–35. CUSIP number (multiple entries allowed for electronic filers)
- * (36–44: specific type of suspicious activity) (check all that apply)
36. Structuring
 a. Alters transaction to avoid BSA recordkeeping requirement.
 b. Alters transactions to avoid CTR requirement.
 c. Customer cancels transaction to avoid BSA reporting and recordkeeping requirements
 d. Multiple transactions below BSA recordkeeping threshold.
 e. Multiple transactions below CTR threshold.
- f. Suspicious inquiry by customer regarding BSA reporting or recordkeeping requirements
- z. Other (specify type of suspicious activity in space provided)
37. Casinos
 a. Minimal gaming with large transactions
 b. Suspicious intra-casino funds transfers
 c. Suspicious use of counter checks or markers
 z. Other (specify type of suspicious activity in space provided)
38. Fraud
 a. Check
 b. Commercial loan
 c. Commercial mortgage loan
 d. Consumer loan
 e. Credit/Debit card
 f. Elder financial abuse
 g. Healthcare
 h. Mail
 i. Mass-marketing
 j. Pyramid scheme
 k. Residential mortgage loan
 l. Wire
 z. Other (specify type of suspicious activity in space provided)
39. Identification
 a. Changes spelling or arrangement of name
 b. Multiple individuals with same or similar identities
 c. Provided questionable or false documentation
 d. Refused or avoided request for documentation
 e. Single individual with multiple identities
 z. Other (specify type of suspicious activity in space provided)
40. Insurance
 a. Excessive insurance
 b. Excessive or unusual cash borrowing against policy/annuity
 c. Little or no concern for product performance, penalties, fees, or tax consequences
 d. Proceeds sent to unrelated third party
 e. Suspicious life settlement sales (e.g. STOLI's, Viaticals)
 f. Suspicious termination of policy or contract
 g. Unclear or no insurance interest
 z. Other (specify type of suspicious activity in space provided)
41. Securities/Futures/Options
 a. Insider trading
 b. Market manipulation/wash trading
 c. Misappropriation
 d. Unauthorized pooling
 z. Other (specify type of suspicious activity in space provided)
42. Terrorist Financing
 a. Known or suspected terrorist/terrorist organization
 z. Other (specify type of suspicious activity in space provided)
43. Money laundering
 a. Exchanges small bills for large bills or vice versa
 b. Suspicion concerning the source or physical condition of funds
 c. Suspicious currency exchanges
 d. Suspicious designation of beneficiaries, assignees or joint owners
 e. Suspicious EFT/Wire transfers
 f. Suspicious receipt of government payments/benefits
 g. Suspicious use of multiple accounts
 h. Suspicious use of noncash monetary instruments
 i. Suspicious use of third-party transactors (straw-man)
 j. TBML/BMPE
 k. Transaction with no apparent economic, business, or lawful purpose.
 l. Transaction out of pattern for customer(s)
 z. Other (specify type of suspicious activity in space provided)
44. Other suspicious activities
 a. Bribery or gratuity
 b. Counterfeit checks
 c. Embezzlement/theft/disappearance of funds
 d. Forgeries
 e. Identity theft
 f. Misuse of position or self-dealing
 g. Suspected public/private corruption (domestic)
 h. Suspected public/private corruption (foreign)
 i. Suspicious use of informal value transfer system
 j. Suspicious use of multiple locations
 k. Two or more individuals working together
 l. Unauthorized electronic intrusion
 m. Unlicensed or unregistered MSB
 z. Other (specify type of suspicious activity in space provided)
- Part III Information Concerning Financial Institution Where Activity Occurred
- * 45. Type of financial institution (check only one)
 a. Casino/Card club
 b. Depository institution
 c. Insurance company
 d. MSB
 e. Securities/Futures
 z. Other (specify type of institution in space provided)
- * 46. Primary Federal Regulator (instructions specify banking agencies, CFTC, SEC)
 CFTC
 Federal Reserve
 FDIC
 FinCEN (Including where IRS or another FinCEN delegate examines for compliance)

- NCUA
OCC
OTS
SEC
Not Applicable
47. Filing institution identification number (Check one box to indicate type)
- CRD number
 - IARD number
 - NFA number
 - SEC ID number
 - RSSD number
 - Identification number
48. If item 45a is checked, indicate type of gaming institution
- State licensed casino
 - Tribal authorized casino
 - Card club
 - Other (specify type of gaming institution in space provided)
49. If item 45e is checked, indicate type of Securities and Futures institution or individual where activity occurred—check box(es) for functions that apply to this report
- Clearing broker—securities
 - Futures commission merchant
 - Holding company
 - Introducing broker—commodities
 - Introducing broker—securities
 - Investment advisor
 - Investment company
 - Retail foreign exchange dealer
 - Subsidiary of financial/bank holding company
 - Other (specify type of institution or individual in space provided)
- * 50. Legal name of financial institution
51. Alternate name, e.g., AKA—individual or trade name, DBA—entity
- * 52. TIN (enter number in space provided and check appropriate type below)
- (check if) unknown
53. TIN type (* if 52 is completed)
- EIN
 - SSN—ITIN
 - Foreign
- * 54. Address
- (check if) unknown
- * 55. City
- (check if) unknown
56. State
- State should be derived through third party data as enhanced data if not provided and Country is US, Mexico or Canada and ZIP/Postal Code is provided
- * 57. ZIP/Postal Code
- (check if) unknown
- ZIP + 4 should be derived through third party data as enhanced data if not provided or verified through third party data if provided
- New Data Element of County—Derived through third party data as enhanced data
- * 58. Country (2 letter code—list provided)
59. Internal control/file number
60. Loss to financial institution (if applicable)
61. Financial institution's role in transaction (if applicable)
- (check if) Selling location
 - (check if) Paying location
 - (check if) Both a & b
- * 62. Address of branch or office where activity occurred (if no branch activity involved, check box a)
63. RSSD number (of the Branch)
64. City
65. State
- State should be derived through third party data as enhanced data if not provided and Country is US, Mexico or Canada and ZIP/Postal Code is provided
66. ZIP/Postal Code
- ZIP + 4 should be derived through third party data as enhanced data if not provided or verified through third party data if provided
- New Data Element of County—Derived through third party data as enhanced data
- New Data Elements for GEO Coding—Derived through third party data as enhanced data will be identified for the financial institution and any branches provided.
- New Data Element of HIFCA code—Derived through third party data as enhanced data will be identified for the financial institution and any branches provided.
- New Data Element of HIDTA code—Derived through third party data as enhanced data will be identified for the financial institution and any branches provided.
67. Country (2 letter code—list provided)
68. Branch's role in transaction (if applicable)
- (check if) Selling location
 - (check if) Paying location
 - (check if) Both a & b
- (paper filers have space to enter 2 branches—items 69–75; electronic filers can enter multiple branches)
- Part IV Filing Institution Contact Information
- * 76. Primary Federal Regulator (instructions specify banking agencies, SEC, CFTC,) CFTC
Federal Reserve
FDIC
FinCEN (Including where IRS or another FinCEN delegate examines for compliance)
NCUA
OCC
- OTS
SEC
Not Applicable
- * 77. Filer name
- * 78. TIN (enter number in space provided and check appropriate type below)
- * 79. TIN type
- EIN
 - SSN/ITIN
 - Foreign
- * 80. Type of financial institution (check only one)
- Casino/Card club
 - Depository institution
 - Insurance company
 - MSB
 - Securities/Futures
 - Other (specify type of institution in space provided)
81. Type of Securities and Futures institution or individual filing this report—check box(es) for functions that apply to this report
- Clearing broker—securities
 - CPO/CTA
 - Futures commission merchant
 - Holding company
 - Introducing broker—commodities
 - Introducing broker—securities
 - Investment advisor
 - Investment company
 - Retail foreign exchange dealer
 - SRO Futures
 - SRO Securities
 - Subsidiary of financial/bank holding company
 - Other (specify type of institution or individual in space provided)
82. Filing institution identification number (Check one box to indicate type)
- CRD number
 - IARD number
 - NFA number
 - SEC ID number
 - RSSD number
 - Identification number
- * 83. Address
- * 84. City
85. State
- State should be derived through third party data as enhanced data if not provided and Country is US, Mexico or Canada and ZIP/Postal Code is provided
- * 86. ZIP/Postal Code
- ZIP + 4 should be derived through third party data as enhanced data if not provided or verified through third party data if provided
- New Data Element of County—Derived through third party data as enhanced data
- * 87. Country (2 letter code—list provided)
88. Alternate name, e.g., AKA—individual or trade name, DBA—entity

- | | | |
|--|--|---|
| * 89. Internal control/file number | a. Extension, if any | (for electronic filers one attachment permitted—Excel-compatible file, 1 MB maximum size) |
| 90. LE contact agency | * 96. Designated office e-mail address | |
| 91. LE contact name | * 97. Date filed | [FR Doc. 2010-26038 Filed 10-14-10; 8:45 am] |
| 92. LE contact phone number | * Part V Suspicious Activity Information—Narrative | BILLING CODE 4810-02-P |
| a. Extension (if any) | | |
| 93. LE contact date | | |
| * 94. Designated contact office | | |
| * 95. Designated contact office phone number including area code | (text field 17,000 characters) | |



Federal Register

**Friday,
October 15, 2010**

Part II

Federal Trade Commission

**16 CFR Part 260
Guides for the Use of Environmental
Marketing Claims; Proposed Rule**

FEDERAL TRADE COMMISSION**16 CFR Part 260****Guides for the Use of Environmental Marketing Claims****AGENCY:** Federal Trade Commission.**ACTION:** Proposed revisions to guidelines.

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) conducted a comprehensive review of its Guides for the Use of Environmental Marketing Claims (“Green Guides” or “Guides”) and proposes retaining the Guides. After reviewing the public comments, the transcripts of three public workshops that explored emerging issues, and the results of its consumer perception research, the Commission proposes several modifications and additions to the Guides. These proposed revisions aim to respond to changes in the marketplace and help marketers avoid making unfair or deceptive environmental marketing claims. The Commission seeks comment on these proposed revisions and other issues raised in this document.

DATES: Comments must be received on or before December 10, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form, by following the instructions in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Comments in electronic form should be submitted at (<https://ftcpublish.commentworks.com/ftc/revisegreenguides>) (and following the instructions on the web-based form). Comments in paper form should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580, in the manner detailed in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below.

FOR FURTHER INFORMATION CONTACT: Laura Koss, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 202-326-2890.

SUPPLEMENTARY INFORMATION:**I. Overview**

Environmental marketing claims are useful sources of information for consumers, but only when they are true. Ensuring that such claims are truthful is particularly important because consumers often cannot determine for themselves whether a product, package,

or service actually possesses the advertised environmental attribute. Because there is a potential for consumer confusion about environmental claims, guidance from the FTC can benefit both businesses and consumers alike.

To help marketers make truthful and substantiated environmental claims, the Federal Trade Commission issued the Guides for the Use of Environmental Marketing Claims (“Green Guides” or “Guides”) in 1992, and revised them in 1996 and 1998. The Guides help marketers avoid making deceptive claims by outlining general principles that apply to all environmental marketing claims and providing specific guidance about how reasonable consumers are likely to interpret particular claims, how marketers can substantiate them, and how they can qualify those claims to avoid consumer deception.

Periodic review ensures that the Guides keep pace with evolving consumer perceptions and new environmental claims. Since the FTC last revised them in 1998, the marketplace has been dynamic. As consumers have become increasingly concerned about the environmental impact of the products and services they use, marketers have expanded their promotion of the environmental attributes of their products and services. Some of these promotions have prompted enforcement action by the FTC, including cases challenging certain environmental benefit claims as false, such as “degradable” paper products or so-called “bamboo” textiles that are made with an “eco-friendly manufacturing process.” And, an increasing number of environmental claims are new or were not common when the Guides were last reviewed and, therefore, are not addressed by the current Guides. Thus, beginning in 2007, the FTC sought public comments on the continuing effectiveness of the Guides, held public workshops on emerging green marketing issues, and conducted research on consumer perception of environmental claims. This review affirms that the Guides have benefitted consumers and businesses but suggests that the Guides should be updated.

The FTC, therefore, proposes several revisions to the Guides. Many of these revisions strengthen, add specificity to, or enhance the accessibility of the current guidance on general “green” claims and environmental seals, and claims such as compostable, degradable, and recyclable. Others propose new guidance regarding emerging claims not currently addressed in the Guides, such

as renewable materials, renewable energy, and carbon-offsets. The FTC also proposes non-substantive changes throughout the Guides to make them easier to read and use, including simplifying language and reorganizing sections to make information easier to find. The FTC is now seeking further public comment on each of these proposed modifications to the Guides.

First, the FTC proposes strengthening its guidance regarding general environmental benefit claims. The FTC’s consumer perception study confirms what the current Guides already state — unqualified claims that an item is “environmentally friendly” or “eco-friendly” are likely to convey that it has specific and far-reaching environmental benefits. Very few products, if any, have all of the attributes consumers seem to perceive from such claims. Therefore, these claims may be impossible to substantiate. Accordingly, the proposed guidance cautions marketers not to make unqualified general claims. Our study indicates, however, that marketers may be able to effectively qualify these claims to focus consumers on the specific environmental benefits that marketers could substantiate. Therefore, the proposed revised Guides provide more prominent guidance on how to adequately qualify general environmental claims.

Similarly, the proposed revised Guides include a new section devoted to certifications and seals of approval, which currently are addressed in a single example. The proposed new section gives more prominence to the current Guides’ admonition that unqualified seals of approval and certifications likely constitute general environmental benefit claims. It also more directly cautions marketers not to use unqualified certifications or seals, i.e., certifications or seals that do not state the basis for the certification. The proposed section further advises marketers that qualifications should be clear and prominent and should convey that the certification or seal of approval refers only to specific and limited benefits. Moreover, this new section emphasizes that certifications and seals of approval constitute endorsements covered by the FTC’s Endorsement Guides and includes examples explaining how those Guides apply to environmental claims.

The proposed revised Guides also suggest clarification for claims that a product is degradable, compostable, or “free of” a particular substance, and highlight guidance for recyclable claims. If a marketer claims, in certain cases, that a product is “degradable,” it should

decompose in a “reasonably short period of time” — no more than one year. Moreover, if a solid product is destined for a landfill, an incinerator, or a recycling facility, the marketer should not make unqualified degradable claims because the product will not degrade within a year. Similarly, when making an unqualified “compostable” claim, a marketer should be able to show that the product will break down into usable compost in a safe and timely manner — approximately the same time as the materials with which it is composted. The proposed Guides also clarify and expand guidance about claims that products are “free of” particular materials. Finally, the proposed Guides highlight advice in the current guides that the use of “recyclable” depends on how many consumers and communities have access to recycling facilities for the advertised product.

The proposed revised Guides also include new sections for claims not addressed by the current Guides, such as claims about the use of “renewable materials” and “renewable energy.” The FTC’s consumer perception research suggests that these claims may be misleading because consumers interpret them differently than marketers intend. The proposed new sections advise marketers to provide context for these claims, in the form of specific information about the materials and energy used. Because the FTC’s study did not test the effect of qualifying these claims, however, the FTC specifically seeks comment on whether providing this, or other information, would reduce consumer confusion. The proposed revised Guides also provide advice about “carbon offset” claims: marketers should disclose if the offset purchase funds emission reductions that will not occur within 2 years, should make sure that they do not double count offsets, and should not advertise an offset if the activity that produces the offset is already required by law.

Environmental marketing presents complex, challenging issues. Despite the voluminous record established by this review, the FTC would benefit from additional input in many areas, including for the claims discussed above and also for “organic” and “made with recycled content” claims. Therefore, the FTC invites comment on all aspects of the proposed revised Guides, as well as on the specific questions it poses in this Notice. The FTC will take all suggestions into account as it works to finalize the revised Guides.

II. Background

A. *The Green Guides*

The Commission issued the Green Guides, 16 CFR Part 260, to help marketers avoid making environmental claims that are unfair or deceptive under Section 5 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. 45.¹ Industry guides, such as these, are administrative interpretations of the law. Therefore, they do not have the force and effect of law and are not independently enforceable. The Commission, however, can take action under the FTC Act if a marketer makes an environmental claim inconsistent with the Guides. In any such enforcement action, the Commission must prove that the challenged act or practice is unfair or deceptive.

The Green Guides outline general principles that apply to all environmental marketing claims and provide specific guidance regarding many environmental benefit claims. For each such claim, the Green Guides explain how reasonable consumers are likely to interpret the claim, describe the basic elements necessary to substantiate the claim, and present options for qualifying the claim to avoid deception.² The illustrative qualifications provide guidance for marketers who want assurance about how to make nondeceptive environmental claims, but do not represent the only permissible approaches to qualifying a claim. This guidance assists marketers in making truthful and substantiated statements about the environmental attributes of their products and services.

In order to adequately substantiate environmental marketing claims, the Guides advise marketers that they will often need “competent and reliable scientific evidence.”³ The Guides currently define competent and reliable scientific evidence as “tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, conducted and

evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁴ Since the last Green Guides review, the Commission has clarified this standard, stating that such evidence “should be sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that [a] representation is true.”⁵

B. *The Green Guides Review*

1. First Request for Public Comment⁶

Since the Commission last revised the Green Guides in 1998, both anecdotal evidence and empirical research indicate that consumers have a heightened awareness of environmental concerns and, therefore, place increased importance on buying products and services that will cause less harm to the environment.⁷ Marketers, in turn, have responded by touting the environmental attributes of their products and services. Because of the proliferation of these environmental claims, the Commission began its decennial Guides review on November 26, 2007, one year before scheduled. The Commission’s

⁴ *Id.*

⁵ See, e.g., *Indoor Tanning Ass’n*, Docket No. C-4290 (May 13, 2010) (consent order); see also *Dietary Supplements: An Advertising Guide for Industry* (2001), available at (<http://www.ftc.gov/bcp/edu/pubs/business/ad/bus09.pdf>) (stating that “the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence”).

⁶ Citations to comments identify the commenter, the particular *Federal Register* Notice to which the commenter responded (533431– Green Guides Review; 533254 – Carbon Offsets and Renewable Energy Certificates Workshop; 534743 – Green Packaging Workshop; or 536013 – Green Building and Textiles Workshop), and the assigned comment number.

⁷ See, e.g., American Chemistry Council (“ACC”), Comment 533431-00023 at 3 (citing a 2005 nationwide survey finding that 90 percent of consumers base their buying decisions, in part, on the effect their choices will have on the environment); Environmental Packaging International (“EPI”), Comment 533431-00063 at 8 (citing studies by the Natural Marketing Institute, Landor Associates, Datamonitor, Organic Consumers Association, and Global Marketing Insight); Saint-Gobain Corporation (“Saint-Gobain”), Comment 533431-00037 at 5-6 (citing studies by Consumers International, American EnviroNics, EcoPinion); Seventh Generation, Comment 533431-00033 at 2 (citing 2007 Cone Consumer Environmental Survey); American Beverage Association (“ABA”), Comment 533431-00066 at 2-3; Dow Chemical Company (“Dow”), Comment 533431-00010 at 1; North American Insulation Manufacturers Association (“NAIMA”), Comment 536013-00017 at 5-6; Procter & Gamble Company (“P&G”), Comment 533431-00070 at 1; The Advertising Trade Associations (“ATA”), Comment 533431-00041 at 7.

¹ The Commission issued the Green Guides in 1992 (57 FR 36363 (Aug. 13, 1992)), and subsequently revised them in 1996 (61 FR 53311 (Oct. 11, 1996)) and 1998 (63 FR 24240 (May 1, 1998)). The FTC administers several other environmental and energy-related rules and guides. See *Guide Concerning Fuel Economy Advertising for New Automobiles* (16 CFR Part 259), *Appliance Labeling Rule* (16 CFR Part 305), *Fuel Rating Rule* (16 CFR Part 306), *Alternative Fuels and Alternative Fueled Vehicles Rule* (16 CFR Part 309), *Recycled Oil Rule* (16 CFR Part 311), and *Labeling and Advertising of Home Insulation Rule* (16 CFR Part 460).

² The Guides, however, do not establish standards for environmental performance or prescribe testing protocols.

³ 16 CFR 260.5.

November 2007 **Federal Register** Notice sought comment on a number of general issues, including the continuing need for and economic impact of the Guides, the effect of the Guides on the accuracy of environmental claims, and whether the Commission should provide guidance on certain environmental claims – such as carbon neutral, sustainable, and renewable – not currently addressed in the Guides.⁸ The Commission received 75 written comments in response.

2. Workshops and Corresponding Requests for Public Comment

To establish a more robust record, the Commission also held three public workshops to explore emerging environmental marketing claims. Specifically, the workshops addressed carbon offsets and renewable energy certificates;⁹ green packaging claims;¹⁰ and green building and textiles.¹¹ The workshops brought together over 450 people representing industry, government, consumer groups, the academic community, and non-profit environmental organizations.¹² The Commission requested comment in connection with each workshop¹³ and received an additional 125 written comments.¹⁴

3. Consumer Perception Evidence

Because the Guides are based on consumer understanding of environmental claims, consumer perception research can provide the Commission with the best evidence upon which to formulate guidance. The following discusses commenters' submissions of consumer research and

the Commission's 2009 consumer perception study.

a. Commenters' Submissions

Although the Notices solicited consumer perception evidence, few commenters submitted such research.¹⁵ Rather, commenters submitted research concerning: (1) consumers' attitudes and beliefs about environmental claims;¹⁶ (2) consumers' environmental concerns and interests;¹⁷ and (3) consumers' behavior regarding environmental claims.¹⁸ These surveys do not provide a basis upon which the Commission can formulate guidance on how to make truthful and nondeceptive environmental marketing claims. Accordingly, the Commission conducted its own consumer perception study in July and August of 2009.

b. The Commission's Consumer Perception Study

To conduct the study, the FTC contracted with Harris Interactive, a

consumer research firm with substantial experience surveying consumer communications.¹⁹ The study sampled members of the contractor's Internet panel, which consists of more than four million individuals recruited through a variety of convenience sampling procedures.²⁰ From this sample, Harris selected individuals who were invited to complete the survey. Participants were selected to correspond, as much as possible, with the known distribution of U.S. adults aged 18 and over in terms of age, gender, race and ethnicity, and geographic region. A total of 3,777 individuals completed the survey.²¹

Harris presented participants with several questions aimed at determining how they understand certain environmental claims. The first portion of the study tested the following claims: "green," "eco-friendly," "sustainable," "made with renewable materials," "made with renewable energy," and "made with recycled materials." The questionnaire asked about both unqualified and qualified general environmental benefit claims (e.g., "green" vs. "green - made with recycled materials"), as well as specific-attribute claims alone (e.g., "made with recycled materials"). The study tested these claims against a non-environmental control claim (e.g., "new and improved"). Moreover, to examine whether consumers' understanding of the claims differed depending on the product being advertised, the study tested the claims as they appeared on three different products – wrapping paper, a laundry basket, and kitchen flooring.²² Harris tested 16 different claims with each of the three different products, resulting in a total of 48 product-claim pairs. To avoid skewing an individual's answers by asking the same person essentially the same set of questions multiple times, and to limit the length of the survey presented to any individual, each participant was

¹⁵ The Commission discusses the consumer perception research that commenters submitted in the substantive parts of this Notice.

¹⁶ ACC, Comment 536013-00030 at 2 (citing a survey of consumer descriptions of a "green company"); Rick L. Cantrell, Sustainable Forestry Initiative, Inc. ("SFI"), Green Building and Textiles Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/buildingandtextiles/presentations/3rcantrell.pdf>) (citing a survey regarding consumer concerns about "sustainable forestry"); P&G, Comment 533431-00070 at 1 (citing a study of consumer consideration of "sustainability factors" in purchasing decisions); Kelly Tullier, Grocery Manufacturers Association ("GMA"), Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/tullier.pdf>) (same); U.S. Green Building Council ("USGBC"), Comment 536013-00029 at 2 (citing a study regarding consumer knowledge of green homebuilding).

¹⁷ John Kalkowski, Packaging Digest ("Packaging Digest"), Green Packaging Workshop Tr. at 22-23 (citing a study concerning consumers' lack of interest in environmental activities); Patricia F. O'Leary, Cotton Incorporated ("Cotton Incorporated"), Green Building and Textiles Workshop Tr. at 28 (citing a study regarding consumers' reaction to apparel items that are not "environmentally friendly"); NAIMA, Comment 536013-00027 at 4-5 (citing a study regarding consumers' concern about global warming); Saint-Gobain, Comment 533431-00037 at 4-5 (same); Seventh Generation, Comment 533431-00033 at 2 (citing studies of consumers' interest in the environment).

¹⁸ GMA, Green Packaging Workshop Tr. at 111 (citing a survey concerning consumer Internet use to get information about environmental initiatives and products); National Recycling Coalition ("NRC"), Comment 533431-00078 at 2 (discussing its research concerning consumers' recycling behavior); Sam Rashkin, Environmental Protection Agency, Green Building and Textiles Workshop Tr. at 178-179 (citing a survey concerning consumer awareness of the Energy Star name and logo); Kirsten Ritchie, Gensler ("Gensler"), Green Building and Textiles Workshop Tr. at 109 (same); Timothy Smith, University of Minnesota ("Univ. of Minnesota"), Comment 536013-00004 at 1 (citing a study examining life cycle information in advertising).

¹⁹ The Commission's consumer perception study is available at (<http://www.ftc.gov/green>).

²⁰ The sample for this research, therefore, does not necessarily constitute a true, random sample of the adult U.S. population. However, because the study focused primarily on comparing responses across randomly assigned treatment groups, the Internet panel provided an appropriate sample frame.

²¹ Additional detail on sample selection is available in the methodology report prepared by Harris which is available at (<http://www.ftc.gov/green>).

²² The study results support the current Guides' approach of providing general, rather than product-specific, guidance because consumers generally viewed the tested claims similarly for the three tested products. Moreover, the results were comparable for respondents who indicated concern and interest in environmental issues and those who did not.

⁸ 72 FR 66091 (Nov. 27, 2007). This review has taken some time because, in order to provide as useful advice as possible, the Commission conducted a consumer perception study of certain environmental marketing claims. The Commission discusses this study in detail below.

⁹ See 72 FR 66094 (Nov. 27, 2007).

¹⁰ See 73 FR 11371 (Mar. 3, 2008).

¹¹ See 73 FR 32662 (June 10, 2008).

¹² Citations to workshop transcripts or presentations identify the speaker's name and organization, the relevant workshop, and either the transcript page or the hyperlink to the speaker's presentation.

¹³ Documents relating to the Green Guides review, including the public comments; workshop agendas, presentations, and transcripts; and the Commission's consumer perception study are available at (<http://www.ftc.gov/green>).

¹⁴ The Union of Concerned Scientists submitted a comment containing letters from over 16,000 individuals. Although approximately 1,300 of those letters vary in form, the substance of all the letters is the same. They urged the FTC to review the environmental marketing of corn-based ethanol as a "green" alternative to gasoline. The comments suggested that such marketing is not based on "sound science" because corn ethanol production could cause an increase in the production of global warming pollution over regular gasoline.

asked questions regarding only two randomly-selected product-claim pairs.

The second portion of the study tested carbon offset and carbon neutral claims. The questionnaire asked half of the participants about carbon offsets and half about carbon neutral claims. An initial screening question gauged whether respondents understood these concepts by asking them to identify what a carbon offset was or what carbon neutral meant. Only those participants who demonstrated a general understanding of these terms continued with the remainder of the study.

Both portions of the study used a combination of open- and closed-ended questions exploring the same topic. The study questionnaire described the claims to participants, rather than presenting an actual advertisement. For example, a participant was asked: "Suppose you see some wrapping paper advertised or labeled as 'green - made with recycled materials.'"

After the study's completion, Harris provided FTC staff with data summaries. The results of this study are discussed below in Parts IV.F, V, and VI of this Notice.²³

C. Outline of This Notice

After reviewing the public comments, the workshop proceedings, and the consumer perception evidence, the Commission proposes retaining the Green Guides and making several revisions. Part III of this Notice proposes three non-substantive changes to make the Guides easier to read and use. Part IV discusses comments on general issues, such as the continuing need for the Guides and general comments on life cycle analysis. Part V discusses issues relating to specific claims that already are addressed by the Guides. Part VI addresses environmental marketing claims not currently covered by the Guides. Part VII requests public comment on the issues raised in this Notice, including the proposed, revised Green Guides. Finally, Part VIII sets out the proposed, revised Guides.

III. Proposed Non-substantive Changes to the Current Green Guides

The Commission proposes three changes to make the Guides easier to read and use. First, wherever possible, the Commission has simplified the Guides' language to make it clearer and easier to understand. For example, the FTC has replaced its formal, legal

description of the Guides in Section 260.1 with a more reader-friendly version. Similarly, the Commission has removed unnecessary language and redundant examples from all sections of the Guides.²⁴

Second, the Commission proposes reorganizing the Guides. Specifically, the proposed, revised Guides combine the first three sections into one section, which discusses the Guides' purpose, scope, and structure. In addition, the Commission proposes splitting existing Section 260.7 (titled "Environmental Marketing Claims") into multiple sections. Currently, Section 260.7 provides advice on eight different environmental claims, containing the bulk of the Commission's guidance. To make the information easier to find, the Commission proposes moving each environmental claim into its own section, organized alphabetically, and dividing the guidance within each section into subparts (e.g., section 260.9(a), 260.9(b), etc.). Because of these organizational changes, the Commission has renumbered each Guide section.

Third, the Commission proposes deleting Sections 260.4 and 260.8. Section 260.4 states that the Commission reviews the Green Guides as part of its ongoing, periodic review program, and explains that parties may petition the Commission to amend the Guides in light of new evidence. This information is common to all of the Commission's guides, and it is unnecessary to repeat it in each one.²⁵ Section 260.8 contains the FTC's environmental assessment of the Guides pursuant to the National Environmental Policy Act. Because this information is contained in the **Federal Register** Notice that enacted the Guides and is not needed by marketers using the Guides, the Commission proposes deleting it from the Guides' text.²⁶ These deletions

²⁴ Among other things, the Commission proposes deleting from Section 260.5 a reference to the FTC's law enforcement actions in the green area and the telephone number to call to obtain copies of those cases. Case information may be found on the Commission's website, (<http://www.ftc.gov>). In addition, in Section 260.2, the Commission proposes deleting the explicit statement that the Guides apply to "marketing through digital or electronic means." The Commission added this reference in 1998, when Internet marketing was emerging and online advertisers were uncertain about the Guides' applicability. Because Internet marketing is now ubiquitous, the Commission proposes revising the Guides to state that they apply to marketing in any medium.

²⁵ Information about petitioning the FTC may be found in the Commission's rules. See, e.g., 16 CFR 1.6.

²⁶ As we did when issuing the Guides in 1992 and revising them in 1996 and 1998, the Commission concludes that the proposed revisions to the Guides would not have a significant impact on the environment and any such impact "would

will streamline the Guides, making them a more user-friendly document.

IV. General Issues

The Commission sought comment on several general issues, including: (1) whether there is a continuing need for the Guides; (2) whether, and to what degree, industry is complying with the Guides; (3) whether the Commission should modify the Guides due to changes in technology or economic conditions; (4) whether there are international laws or standards the FTC should consider as part of its review; and (5) whether the Guides overlap or conflict with other federal, state, or local laws or regulations. This section discusses the commenters' responses to these questions, as well as their views on life cycle analysis, and provides the Commission's analysis of the issues.

A. Continuing Need for the Guides

1. Comments

Several commenters affirmed that the Guides have benefitted consumers by stemming the tide of spurious environmental claims; bolstering consumer confidence; imposing clarity and consistency in environmental marketing claims; and increasing the flow of specific and accurate environmental information to consumers, enabling them to make informed purchasing decisions.²⁷ No

be so uncertain that environmental analysis would be based on speculation." 16 C.F.R. 1.83(a).

²⁷ See, e.g., ACC, Comment 533431-00023 at 3-4; ATA, Comment 533431-00041 at 3, 9; American Forest & Paper Association ("AF&PA"), Comment 533431-00019 at 2; American Reusable Textile Association, Comment 534743-00038 at 4; Business for Social Responsibility ("BSR"), Comment 533431-00016 at 1; Carbonfund.org, Comment 533431-00056 at 2; Carpet and Rug Institute ("CRI"), Comment 533431-00026 at 3; Consumer Specialty Products Association ("CSPA"), Comment 533431-00049 at 1-2; Dow, Comment 533431-00010 at 3; EHS Strategies, Inc. ("EHS"), Comment 534743-00011 at 1; Fibre Box Association ("FBA"), Comment 533431-00015 at 1; Georgia-Pacific LLC ("Georgia-Pacific"), Comment 533431-00007 at 1-3; Graphic Arts Coalition, Comment 533431-00060 at 1; GreenBlue, Comment 533431-00058 at 1; Rebecca Hammer ("Hammer"), Comment 533431-00017 at 1-2; Alison C. Healey, et al. ("Healey"), Comment 533431-00048 at 1; International Paper, Comment 533431-00055 at 1; MeadWestvaco Corporation ("MeadWestvaco"), Comment 533431-00013 at 2; NAIMA, Comment 536013-00042 at 2-3; New York City Department of Consumer Affairs, Comment 533431-00018 at 2; P&G, Comment 533431-00070 at 1; Pratt Industries, Comment 533431-00081 at 1; Lynn Preston ("Preston"), Comment 533431-00021 at 2; Saint-Gobain, Comment 533431-00037 at 2-4; Seventh Generation, Comment 533431-00033 at 7; The Soap and Detergent Association ("SDA"), Comment 533431-00020 at 1, 5; The Society of the Plastics Industry, Inc. ("SPI"), Comment 533431-00036 at 13; U.S. Council for International Business, Comment 533431-00052 at 2; Weyerhaeuser, Comment 533431-00084 at 1.

²³ The methodology used for this study may not be appropriate for testing consumer perception of a particular advertising claim. Among other differences, marketers must test the claim in the context of a specific advertisement, which was impossible here.

commenters suggested the Guides were no longer needed.

Several commenters stated that the Guides help those seeking to make truthful and accurate environmental marketing claims, while providing a level playing field that benefits both consumers and compliant companies.²⁸ Moreover, many agreed that the Guides accomplish their goals without imposing an undue burden on industry.²⁹

2. Analysis

Based on the consensus that the Guides benefit both consumers and businesses, the Commission proposes to retain them. As discussed below, however, the Commission proposes several revisions to ensure that the Guides reflect consumer perception and new claims in the marketplace.

B. Industry Compliance

1. Comments

In response to questions about industry compliance with the Guides, some commenters asserted that deceptive marketing claims have increased in the environmental area.³⁰ For example, TerraChoice Environmental Marketing, Inc. reported the results of its 2007 review of over 1,000 products and expressed concern that many marketers are using vague claims, such as “environmentally friendly” and “green,” without defining terms or providing evidence to support their claims.³¹ It also noted that many marketers “highlight relatively

insignificant environmental benefits of a product while distracting consumers from much more significant impacts.”³² Another commenter observed that companies are marketing the “environmentally friendly” nature of their products “through words or pictures while only minimally (if at all) qualifying such claims.”³³ In addition, other commenters noted increased instances of “greenwashing” by marketers using a “plethora of buzzwords like sustainable, environmentally friendly, carbon offsets, [and] green.”³⁴ Some commenters suggested that bringing more enforcement actions could help address this issue.³⁵

Commenters also expressed concern that the Guides may not be effectively reaching industry because many businesses are unfamiliar with them or do not realize that they apply to business-to-business transactions.³⁶ For example, one commenter asserted that the Guides have provided no benefit to the small business community, stating that key players in the printing industry do not know about the Green Guides.³⁷ Packaging workshop panelist Environmental Packaging International described a visit to a recent packaging trade show and noted that, in its estimation, 20 percent of the exhibitors were making misleading claims about the environmentally preferable qualities of their packaging.³⁸

Panelist NatureWorks LLC echoed this concern, noting that even industry members familiar with the Guides are not aware that they apply to business-

to-business transactions.³⁹ Workshop panelists, therefore, recommended that the Guides emphasize their application to business-to-business transactions and not just business-to-consumer marketing.⁴⁰ Environmental Packaging International proposed, for instance, that the Guides include specific examples of such business-to-business transactions.⁴¹

2. Analysis

The Guides’ purpose is to help marketers avoid making unfair or deceptive environmental claims. For marketers who nevertheless violate the law, the Commission will continue its enforcement efforts. The Commission brought several recent actions involving false or unsubstantiated environmental claims. For example, last year, the Commission announced three actions charging marketers with making false and unsubstantiated claims that their products were biodegradable.⁴² In addition, the Commission charged four sellers of clothing and other textile products with deceptively labeling and advertising these items as made of bamboo fiber, manufactured using an environmentally friendly process, and/or biodegradable.⁴³

The Commission proposes revising the Guides to state more clearly that they apply to business-to-business transactions and not just business-to-

²⁸ See, e.g., International Paper, Comment 533431-00055 at 2 (noting that the Guides level the playing field by standardizing terms and requiring factual bases for claims); AF&PA, Comment 533431-00083 at 2; CSPA, Comment 533431-00049 at 1-2; EPI, 533431-00063 at 2; MeadWestvaco, Comment 533431-00013 at 1; NAIMA, Comment 536013-00017 at 2.

²⁹ See, e.g., GreenBlue, Comment 533431-00058 at 3 (stating that the Guides’ assurance of accuracy and specificity actually reduces costs “by providing a more common, consistent framework for communicating product attributes”); AF&PA, Comment 533431-00083 at 2; ATA, Comment 533431-00041 at 7-9; Saint-Gobain, Comment 533431-00037 at 6-7.

³⁰ See, e.g., MeadWestvaco, Comment 533431-00013 at 1 (noting that diligent companies are disadvantaged by those companies that ignore or do not understand the Guides and capitalize on growing interest in environmental issues); Saint-Gobain, Comment 533431-00037 at 3 (commenting that manufacturers continue to make deceptive claims, particularly in insulation and building industries); TerraChoice Environmental Marketing, Inc. (“TerraChoice”), Comment 533431-00040 at 1-4 (stating that the use of false or misleading claims is rampant); GreenBlue, Comment 533431-00058 at 4-6. *But see* ATA, Comment 533431-00041 at 3 (stating that no evidence suggests that consumers are being misled by claims); Georgia-Pacific, Comment 533431-00007 at 5 (commenting that there is a high degree of industry compliance).

³¹ TerraChoice, Comment 533431-00040 at 3, 6.

³² *Id.* at 1.

³³ Jim Krenn (“Krenn”), Comment 533431-00014 at 3.

³⁴ Phil Bailey (“Bailey”), Comment 533431-00028 at 3; *see also* Hammer, 533431-00017 at 4-5; Healey, Comment 533431-00048 at 2-5.

³⁵ GreenBlue, Comment 533431-00058 at 4; International Paper, Comment 533431-00055 at 3; MeadWestvaco, Comment 533431-00013 at 2; Eric Nguyen, Comment 533431-00009 at 5-6; SDA, Comment 533431-00020 at 5; Seventh Generation, Comment 533431-00033 at 7.

³⁶ Joseph Cattaneo, Glass Packaging Institute (“GPI”), Green Packaging Workshop Tr. at 249, 251 (noting that marketers are not paying attention to the Guides when creating their campaigns); ACC, Comment 536013-00030 at 3; Cheryl Baldwin, Green Seal (“Green Seal”), Green Packaging Workshop Tr. at 192; Victor Bell, EPI (“EPI”), Green Packaging Workshop Tr. at 232-233; Michelle Harvey, Environmental Defense Fund (“EDF”), Green Packaging Workshop Tr. at 53; Packaging Digest, Green Packaging Workshop Tr. at 52. The Guides currently state that they apply to any environmental claim made “in connection with the sale, offering for sale or marketing of the product, package, or service . . . for commercial, institutional, or industrial use.” 16 CFR 260.2.

³⁷ Graphic Arts Coalition, Comment 533431-00060 at 1.

³⁸ EPI, Green Packaging Workshop Tr. at 232-233.

³⁹ See Snehal Desai, NatureWorks LLC (“NatureWorks”), Green Packaging Workshop Tr. at 246-247.

⁴⁰ See, e.g., Scot Case, TerraChoice (“TerraChoice”), Green Packaging Workshop Tr. at 244.

⁴¹ EPI, Green Packaging Workshop Tr. at 252.

⁴² *Dyna-E Int'l, Inc., et al.*, Docket No. 9336 (Dec. 15, 2009); *Knart Corp.*, Docket No. C-4263 (July 15, 2009); *Tender Corp.*, Docket No. C-4261 (July 13, 2009). According to the FTC’s complaints, the defendants’ products typically are disposed in landfills, incinerators, or recycling facilities, where it is impossible for waste to biodegrade within a reasonably short time period.

⁴³ *CSE, Inc., et al.*, Docket No. C-4276 (Dec. 15, 2009); *Pure Bamboo, LLC, et al.*, Docket No. C-4274 (Dec. 15, 2009); *Sami Designs, LLC, et al.*, Docket No. C-4275 (Dec. 15, 2009); *The M Group, Inc., et al.*, Docket No. 9340 (Apr. 2, 2010). According to the complaints, these products are made of rayon, manufactured through a process that uses toxic chemicals and releases hazardous air pollutants, and cannot biodegrade within a reasonably short time period. The Commission also brought five enforcement actions related to deceptive energy claims, involving exaggerated claims about home insulation and false claims about fuel-saving devices for motor vehicles. *See United States v. Enviromate, LLC, et al.*, No. 09-CV-00386 (N.D. Ala. Mar. 2, 2009); *United States v. Meyer Enterprises, LLC, et al.*, No. 09-CV-1074 (C.D. Ill. Mar. 2, 2009); *United States v. Edward Sumpolec*, No. 6:09-CV-379-ORL-35 (M.D. Fla. Feb. 26, 2009); *FTC v. Dutchman Enterprises, LLC, et al.*, No. 09-141-FSH (D.N.J. Jan. 12, 2009); *FTC v. Five Star Auto Club, Inc., et al.*, No. 99-CIV-1963 (S.D.N.Y. Dec. 15, 2008).

consumer marketing.⁴⁴ The proposed, revised section on the “Purpose, Scope, and Structure of the Guides” (260.1) explains that the Guides apply to the marketing of products and services to “individuals, businesses, or other entities.”

Moreover, the proposed, revised Guides include specific business-to-business transaction examples.⁴⁵ Additionally, to increase businesses’ familiarity with the revised Guides, the Commission plans to expand its outreach efforts.

C. Changes in Technology or Economic Conditions

1. Comments

The Notice asked commenters to discuss what modifications, if any, the Commission should make to the Guides to account for changes in relevant technology or economic conditions. In response, many commenters and workshop panelists observed that companies increasingly use the Internet to communicate with consumers about their environmental efforts,⁴⁶ and more consumers use the Internet to check on product claims and learn about products’ environmental attributes.⁴⁷ The Soap and Detergent Association, for example, noted that the “quality and accessibility of online technology has greatly advanced” since the FTC released the Guides.⁴⁸ In its view, company websites have become an increasingly valuable and growing source of clarifying information for consumers about product benefits without the space limitations of packaging.⁴⁹

⁴⁴ A business consumer may interpret a marketer’s claims differently than an individual consumer. As stated in the FTC Policy Statement on Deception (“Deception Policy Statement”), appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984), “[w]hen representations or sales practices are targeted to a specific audience, the Commission determines the effect of the practice on a reasonable member of that group. In evaluating a particular practice, the Commission considers the totality of the practice in determining how reasonable consumers are likely to respond.” Marketers, therefore, must understand how their ads will be interpreted by their customers.

⁴⁵ See Section 260.6, Example 4; Section 260.12, Example 11.

⁴⁶ See, e.g., GMA, Green Packaging Workshop Tr. at 111-115.

⁴⁷ See GMA, Green Packaging Workshop Tr. at 111 (discussing a 2008 online survey showing that 80 percent of the 6,000 consumers interviewed use the Internet to obtain information about environmental initiatives and products); GMA, Comment 533431-00045 at 4; see also Cone LLC, Comment 534743-00007 at 8 (noting that when seeking additional information about a product’s environmental aspects, consumers examine the company’s website, third-party websites, search engines, and the package).

⁴⁸ SDA, Comment 534743-00028 at 4.

⁴⁹ *Id.*

Accordingly, some commenters suggested that the Guides specifically address the Internet and the opportunities it provides for increasing consumer access to product information. For example, the Soap and Detergent Association asked the FTC to determine appropriate circumstances in which information on a company website would be sufficient to explain an environmental claim.⁵⁰ Similarly, NatureWorks stated that the Guides should indicate that “it is acceptable to provide further levels of information on a website.”⁵¹ The Society of the Plastics Industry suggested that the FTC consider allowing qualifiers that refer to websites, which would give companies a means of providing more accurate and detailed information about the availability of recycling facilities than can be provided on a typical package.⁵² According to this commenter, encouraging consumers to visit a website for information on available recycling options would “both empower consumers to educate themselves about recycling options . . . and provide them the necessary roadmap by which to find recycling information quickly and readily, without a significant risk of prompting undesirable consumer behavior (e.g., putting an item that cannot be recycled locally into the curbside recycling bin . . .).”⁵³

Along these lines, EHS Strategies, Inc., noting the pervasiveness of general environmental benefit terms such as “eco” and “green” in marketing, suggested that the Guides recommend that package labeling include a website, telephone number, or address so that consumers can obtain a detailed explanation of a product’s environmental attributes.⁵⁴ However, this commenter cautioned that “[w]hile reference to third-party standards and

⁵⁰ SDA, Comment 534743-00028 at 4. SDA, however, did not set forth these circumstances.

⁵¹ NatureWorks, Green Packaging Workshop Tr. at 230; see also AF&PA, Comment 534743-00031 at 2 (stating that specific sectors should be able to develop focused definitions of sustainability that meet the needs of that sector and that references to websites should be sufficient to provide the necessary explanation).

⁵² SPI, Comment 534743-00034 at 3; see also Brenda Platt, Institute for Local Self-Reliance (“ILSR”), Green Packaging Workshop Tr. at 148 (suggesting that consumers could search a website to identify composting facilities).

⁵³ SPI, Comment 534743-00034 at 4 (emphasis in original).

⁵⁴ EHS, Comment 534743-00011 at 2; see also EnviroMedia Social Marketing, Comment 534743-00032 at 1 (stating that companies making claims about their carbon footprint should be required to list a website to substantiate those claims); TerraChoice, Green Packaging Workshop Tr. at 207 (noting that marketers should make claim substantiation available to consumers via websites and toll-free numbers).

websites are useful, they are likely not . . . investigated by the consumer at point of purchase. Insofar as possible, sufficient point of sale information should be made available to the consumer as to what the environmentally preferred attributes are.”⁵⁵

2. Analysis

Using the Internet, marketers can provide consumers with useful environmental information about products, packages, and services. However, websites cannot be used to qualify otherwise misleading claims that appear on labels or in other advertisements because consumers likely would not see that information before their purchase. Any disclosures needed to prevent an advertisement from being misleading must be clear and prominent and in close proximity to the claim the marketer is qualifying.⁵⁶ These requirements help ensure that consumers notice, read, and understand disclosures to prevent deception.

D. International Laws

1. Comments

The Commission also sought comment on whether it should consider international laws, regulations, or standards with respect to environmental marketing claims in its Guides review. In response, many commenters recommended that the Commission harmonize the Green Guides with the International Organization for Standardization (“ISO”) 14021 environmental marketing standards⁵⁷ or at least incorporate some of its provisions.⁵⁸

For example, one commenter observed that because several countries are in the process of adopting ISO 14021, the FTC should either align the Guides with ISO standards or clarify whether products labeled according to

⁵⁵ EHS, Comment 533431-00057 at 2.

⁵⁶ Deception Policy Statement, 103 F.T.C. at 174.

⁵⁷ ISO is a non-governmental organization which develops voluntary manufacturing and trade standards, including standards for self-declared environmental marketing claims. ISO 14021:1999(E) Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling).

⁵⁸ Dow, Comment 533431-00010 at 4 (noting, however, that the Commission should not follow 14021’s “outdated” prohibition on sustainability); AF&PA, Comment 533431-00019 at 3; CSPA, Comment 533431-00049 at 2; EPI, Comment 533431-00063 at 4; EPA Environmental Preferable Purchasing Program (“EPA-EPPP”), Comment 533431-00038 at 6; FBA, 533431-00015 at 2; Foodservice Packaging Institute (“FPI”), Comment 533431-00074 at 3; Georgia-Pacific, Comment 533431-00007 at 6; GreenBlue, Comment 533431-00058 at 6; MeadWestvaco, Comment 533431-00013 at 2; SDA, Comment 533431-00020 at 2-3.

ISO 14021 comply with the Guides when there is a discrepancy.⁵⁹ Another commenter stressed the importance of “close alignment with global standards,” noting that the discrepancy in how the Green Guides and ISO treat recyclable claims⁶⁰ causes problems with transnational packaging.⁶¹

In addition, several commenters suggested that the FTC look to ISO for guidance on how to conduct a life cycle analysis to ensure consistency in the increasing number of claims using life cycle assessments for substantiation.⁶² Two commenters, however, urged the FTC not to fully harmonize the Green Guides with international standards because “the obstacles and barriers to maintaining, changing or modifying, updating, and revising the system may be enormous” and could cause “tremendous effort and delay.”⁶³

2. Analysis

Because the FTC tries to harmonize its guidance with international standards when appropriate, the Commission gave careful consideration to relevant ISO provisions during the course of its review. The goals and purposes of ISO and the Green Guides, however, are not necessarily congruent. The Guides’ purpose is to prevent the dissemination of misleading claims, not to encourage or discourage particular environmental claims or consumer behavior based on environmental policy concerns. ISO, in contrast, focuses not only on preventing misleading claims, but also on encouraging the demand for and supply of products that may cause less stress on

the environment.⁶⁴ In part because of this difference, the proposed Guides do not necessarily align with the ISO standards. The Commission further discusses ISO standards and any inconsistencies with the proposed Guides in the relevant sections: (1) General Environmental Benefit Claims (Part IV.A); (2) Recyclable Claims (Part IV.E); (3) Recycled Content Claims (Part IV.F); and (4) Free-of and Non-toxic Claims (Part IV.H).

E. Overlap with Other Federal, State, or Local Laws

1. Comments

The Commission sought comment on whether the Guides overlap or conflict with other federal, state, or local laws or regulations, and if so, how. Most commenters did not identify any specific overlap or conflict. Two commenters, however, Saint-Gobain and the North American Insulation Manufacturers Association, expressed concern about the array of guidelines and standards emerging from local, state, and federal government agencies, noting that conflicting and competing guidelines vary in quality and, therefore, consumer utility.⁶⁵ Both commenters urged the FTC to “consider preempting state and local laws and regulations that are inconsistent with or frustrate the purposes of the Guides.”⁶⁶ Neither commenter, however, cited a specific law or regulation.

Commenter Environmental Packaging International noted that the state of California has “more specific requirements than the Guides regarding the use of environmental marketing claims related to plastic packaging.”⁶⁷ For example, EPI stated that California requires that plastic bags and food and beverage containers labeled as “compostable,” “biodegradable,” or “degradable” or marketed using similar terms comply with the applicable ASTM International standard for the term used.⁶⁸ In contrast, the Green

Guides do not refer to a particular industry standard.

International Paper observed that, although it is not aware of any specific conflicts with federal, state, and local laws, the Green Guides may conflict with nongovernmental and international voluntary standards, such as ASTM’s compostability standard.⁶⁹ It recommended that the FTC monitor these standards to try to eliminate any such issues. It also suggested that the FTC coordinate with other federal agencies. For example, it suggested that the FTC coordinate with the Environmental Protection Agency (“EPA”) in the recycling area to make policy and product labeling consistent with current marketplace reality.

Similarly, EPA’s Environmentally Preferable Purchasing Program suggested that the Guides specifically state that “environmentally preferable” claims “should follow established guidance in this area, such as EPA’s Guidance on Environmentally Preferable Purchasing, which emphasizes that such determinations should take into account multiple environmental attributes throughout the product’s life cycle.”⁷⁰

2. Analysis

Based on a review of the comments, the Green Guides do not appear to significantly overlap or conflict with other federal, state, or local laws. Although some commenters discussed the potential for conflict, none cited any particular conflicting laws. State law may be different from the Green Guides, but such differences do not necessarily present a conflict. For example, a company may follow the Green Guides’ provisions on biodegradability and compostability and still comply with California’s specific requirements that plastic bags and containers labeled as “biodegradable” and “compostable” meet ASTM standards.⁷¹ Additionally, although some commenters sought FTC preemption of state and local laws, the Green Guides are not enforceable regulations and, therefore, cannot be legally preemptive.⁷²

One commenter recommended that the Commission coordinate with other federal agencies. The Commission actively consults with other agencies,

and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.

⁵⁹ International Paper, Comment 533431-00055 at 3.

⁷⁰ EPA-EPPP, Comment 533431-00038 at 7.

⁷¹ Indeed, since 1996, California has required marketers to follow the Green Guides. See Cal. Bus. & Prof. Code § 17580-81.

⁷² 16 CFR 260.2.

⁵⁹ AF&PA, Comment 533431-00019 at 3; see also Georgia-Pacific, Comment 533431-00007 at 6.

⁶⁰ ISO states that marketers must qualify recyclable claims if recycling facilities are not conveniently available to a “reasonable proportion” of purchasers where the product is sold. ISO 14021 7.7.2:1999(E). In contrast, the Guides provide that marketers should qualify recyclable claims if recycling facilities are not available to a “substantial majority” of consumers or communities where the product is sold. See 16 CFR 260.7(d), Example 4.

⁶¹ MeadWestvaco, Comment 533431-00013 at 3; see also Georgia-Pacific, Comment 533431-00007 at 6 (suggesting that the Commission address discrepancies such as the definition of “post-consumer” fiber, the references to access to recycling and composting facilities, and the treatment of the Möbius Loop); Paper Recycling Coalition (“PRC”), Comment 533431-00035 at 1 (noting that the Guides should incorporate ISO definitions of recycling and post-consumer recycled content because competing definitions currently cause consumer confusion).

⁶² Georgia-Pacific, Comment 533431-00007 at 3-4 (citing ISO 14040 and 14044); see also ACC, Comment 533431-00023 at 5; GreenBlue, Comment 533431-00058 at 6; P&G, Comment 533431-00070 at 3; Personal Care Products Council (“PCPC”), Comment 533431-00075 at 4; Preston, Comment 533431-00021 at 1; SDA, Comment 533431-00020 at 2-3.

⁶³ NAIMA, Comment 533431-00042 at 12; Saint-Gobain, Comment 533431-00037 at 11-12.

⁶⁴ The introduction to the ISO 14000 series describes the “Objective of environmental labels and declarations” as follows: “The overall goal of environmental labels and declarations is, through communication of verifiable and accurate information, that is not misleading, on environmental aspects of products and services, to encourage the demand for and supply of those products and services that cause less stress on the environment, thereby stimulating the potential for market-driven continuous environmental improvement.” ISO 14020 3:2000(E).

⁶⁵ NAIMA, Comment 533431-00042 at 2, 11; Saint-Gobain, Comment 533431-00031 at 3, 11.

⁶⁶ NAIMA, Comment 533431-00042 at 11; Saint-Gobain, Comment 533431-00031 at 11.

⁶⁷ EPI, Comment 533431-00063 at 4.

⁶⁸ *Id.*, citing Cal. Pub. Res. Code §§ 42355-42357, 42359-42359.6. ASTM International (“ASTM”) is an international standards organization that develops

such as the EPA, the Department of Energy (“DOE”), and the Department of Agriculture (“USDA”), regarding their areas of expertise to ensure that the Commission does not issue guidance that duplicates or possibly conflicts with their regulations and programs. For example, as discussed below, the Commission does not propose specific guidance for organic claims about agricultural products that already are covered by the USDA’s regulations.⁷³

F. Life Cycle Analysis

Life cycle analysis (“LCA”) refers to the assessment of a product’s environmental impact through all the stages of its “life.” The EPA defines the term “life cycle” as “the major activities in the course of the product’s life-span from its manufacture, use, and maintenance, to its final disposal, including the raw material acquisition required to manufacture the product.”⁷⁴ As the EPA notes in its Final Guidance on Environmentally Preferable Purchasing, in the context of making purchasing decisions, the term “life cycle” has several interpretations: “[t]o some, it connotes an exhaustive, extremely time-consuming, and very expensive analysis. To others, a life cycle perspective is possible in an abbreviated process, in which a long list of potential environmental attributes and/or impacts is narrowed to a few, allowing for comparison across a particular product category.”⁷⁵ Accordingly, in its Final Guidance on Environmentally Preferable Purchasing, EPA states that it “promotes the use of a range of practices, from life cycle considerations to a more rigorous, scientifically defensible life cycle assessment methodology.”⁷⁶

The current Green Guides do not provide guidance on life cycle claims. Instead, the Guides include a footnote indicating that the Guides do not address such claims because the Commission “lacks sufficient information on which to base guidance.”⁷⁷

1. Comments

Several commenters discussed whether and how the FTC should provide LCA guidance. Many noted that, since the last Guides review, LCA has become both a more accepted and

better defined process,⁷⁸ and marketers increasingly utilize LCA to assess the environmental effect of their products.⁷⁹ For example, Georgia-Pacific observed that the international expert community in life cycle assessment has developed and agreed on requirements for making environmental comparisons or assertions to the public, which the series of ISO 14040 and 14044 standards reflect.⁸⁰ Other panelists, however, asserted that LCA is still an emerging concept.⁸¹

In particular, commenters discussed: (1) whether marketers should refer directly to LCAs in marketing materials; and (2) whether marketers should substantiate certain claims with an LCA and, if so, whether the Guides should address LCA substantiation methodologies.

a. LCAs as Marketing Claims

Because of the complexity of LCAs, several commenters asserted that life cycle analysis should be regarded as a decision-making tool to help improve environmental outcomes, rather than as a marketing claim.⁸² A participant in the Green Packaging Workshop, Susan Selke, for example, viewed life cycle analysis as “the right philosophical approach” for making decisions, but discouraged its use for communicating information or making claims to consumers, on the grounds that one must “interpret LCA in context for it to be meaningful.”⁸³ Similarly, EHS Strategies, Inc., commented that terms such as “cradle to cradle” and “life cycle” are ill-defined, comprised of

⁷⁸ SDA, Comment 534743-00028 at 3 (noting that procedures for a life cycle analysis are now part of ISO environmental management standards found under ISO 14000); Susan Selke, Michigan State University (“Michigan State Univ.”), Green Packaging Workshop Tr. at 163 (stating that in addition to ISO, there are numerous LCA standards, including certain Canadian standards and standards collected on EPA’s website).

⁷⁹ See, e.g., GMA, Comment 533431-00083 at 10; PCPC, Comment 533431-00075 at 4; SDA, Comment 533431-00020 at 2; SPI, Comment 533431-00036 at 11.

⁸⁰ Georgia-Pacific, Comment 533431-00007 at 7.

⁸¹ See, e.g., Michigan State Univ., Green Packaging Workshop Tr. at 188 (observing that LCA is not yet well understood by industry, academics, or consumers); Thomas R. Reardon, The Business and Institutional Furniture Manufacturer’s Association (“BIFMA”), Green Building and Textiles Workshop Tr. at 246-247.

⁸² John Delfausse, Estée Lauder Companies (“Estée Lauder”), Green Packaging Workshop Tr. at 186; Michigan State Univ., Green Packaging Workshop Tr. at 186; see also ACC, Comment 533431-00023 at 5 (suggesting that LCA can be a useful tool in identifying marketing claims and what type of substantiation or qualification is necessary).

⁸³ Michigan State Univ., Green Packaging Workshop Tr. at 163 (asserting she would “never advocate trying to summarize LCA results on a package”).

multiple factors, and not amenable to understanding on a package label.⁸⁴

In contrast, one commenter reported the results of a study finding that LCA information showing quantitative and specific environmental impact information in an advertisement positively influences consumers’ attitudes toward an advertisement, brand, company, and intention to purchase a product.⁸⁵ The commenter concluded that “LCA-based metrics” may be the best method for effective communication of environmental attributes.⁸⁶ Another commenter stated it would support the use of a standardized label conveying the results of an LCA to consumers, such as an approach akin to the Food and Drug Administration’s (“FDA”) Nutrition Facts Label.⁸⁷

b. LCAs as Substantiation

Commenters also debated whether a full LCA should be required to substantiate environmental claims. While some commenters argued that marketers should be required to conduct a full LCA to support general environmental benefit claims, others argued that this would not be feasible due to inconsistent methodologies, complexity, and expense.⁸⁸

Moreover, some commenters suggested that the Guides could help ensure that companies conducting LCAs do so in a manner that meets the FTC’s substantiation standards.⁸⁹ In particular, the Glass Packaging Institute suggested that the Guides expressly state that LCAs must meet the FTC’s substantiation standard for environmental claims, which requires that marketers have “competent and reliable scientific evidence, defined as tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner by persons qualified to do so,

⁸⁴ EHS, Comment 534743-000211 at 1; see also Estée Lauder, Green Packaging Workshop Tr. at 186 (noting that although consumers are interested in information pertaining to the life cycle and sustainability aspects of packaging, Estée Lauder does not recommend encouraging such claims in the Guides).

⁸⁵ Univ. of Minnesota, Comment 536013-00004 at 1.

⁸⁶ *Id.*

⁸⁷ Estée Lauder, Green Packaging Workshop Tr. at 189 (noting that the Sustainable Packaging Coalition is working on a label concept, and stating that it is important to the industry to have some type of “nutritional” label that will be globally acceptable).

⁸⁸ See Part V.A., *infra*.

⁸⁹ See, e.g., Estée Lauder, Green Packaging Workshop Tr. at 176; GPI, Comment 534743-00026 at 10; SDA, Comment 534734-00026 at 3; Michigan State Univ., Green Packaging Workshop Tr. at 161.

⁷³ See Part VI.B., *infra*.

⁷⁴ See (<http://www.epa.gov/nrmrl/lcaccess/pdfs/600r06060.pdf>).

⁷⁵ See (<http://www.epa.gov/epp/pubs/guidance/finalguidance.htm>).

⁷⁶ *Id.*

⁷⁷ 16 CFR 260.7 n.2.

using procedures generally accepted in the profession to yield accurate and reliable results.⁹⁰ Other commenters went further, noting that because life cycle analyses can vary in requirements and robustness, the Guides should indicate the LCA standards or methodologies that the Commission considers adequate.⁹¹

2. Consumer Perception Evidence

The Commission's study examined whether consumers believe that environmental claims such as "green," "eco-friendly," or "made with recycled materials" suggest anything about the environmental impact of a product through its life cycle.⁹² For consumers who do think about a product's life cycle, the study explored whether they think of more than one stage in that cycle and, if they do, which of the four specific stages (*i.e.*, production, transportation, use, and disposal). Only 16 percent of respondents viewing "green" claims and 14 percent of respondents viewing "eco-friendly" claims thought about each of the life cycle stages.⁹³

3. Analysis

After reviewing the comments and the results of its consumer perception study, the Commission has decided not to propose guidance about the use of life cycle information either in marketing or

as substantiation for environmental claims.⁹⁴ First, the Commission lacks information about how consumers interpret life cycle claims in marketing. Moreover, due to the complexity and variability of these claims, general advice is unlikely to be useful in any particular case. Therefore, the Commission will continue to analyze these claims on a case-by-case basis.

Second, the Commission declines to propose advising marketers either to conduct an LCA to substantiate environmental claims or to follow a particular LCA methodology. Relatively few respondents viewing broad environmental claims (approximately 15 percent) considered each of the life cycle stages. Therefore, the results of the study do not provide a basis for advising marketers to conduct an LCA to substantiate environmental claims. Marketers may rely on the results of an LCA as all, or part of, their substantiation, as long as they ensure that the LCA results constitute competent and reliable scientific evidence to support their claims. The Commission has no basis for choosing one LCA methodology over another. Accordingly, the Commission will continue to apply its substantiation analysis to claims relying on an LCA to determine whether the assessment: (1) has been conducted and evaluated in an objective manner by qualified persons and is generally accepted in the profession to yield accurate and reliable results; and (2) the LCA is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that each of the marketer's claims is true.

V. Claims Addressed by the Current Green Guides

The Commission requested comment on what changes, if any, it should make to its existing guidance on specific claims (currently, in Section 260.7). This part of the Notice summarizes the comments and relevant workshop discussions, reviews the consumer perception evidence, and provides the Commission's analysis of: (1) general environmental benefit claims; (2) certifications and seals of approval; (3) degradable claims; (4) compostable claims; (5) recyclable claims; (6) recycled content claims; (7) ozone-

safe and ozone-friendly claims; (8) free-of and non-toxic claims; (9) source reduction claims; and (10) refillable claims.

A. General Environmental Benefit Claims

1. The Current Guides

The current Guides section on general environmental benefit claims (*e.g.*, "environmentally friendly") states: "[u]nqualified general claims of environmental benefit are difficult to interpret, and depending on their context, may convey a wide range of meanings to consumers. In many cases, such claims may convey that the product, package, or service has specific and far-reaching environmental benefits."⁹⁵ The Guides remind marketers that they have a duty to substantiate "every express and material implied claim that the general assertion conveys to reasonable consumers about an objective quality, feature or attribute of a product." Unless marketers can meet this "substantiation duty," they should avoid, or qualify, these claims "as necessary, to prevent deception about the specific nature of the environmental benefit being asserted."⁹⁶ The following addresses the comments discussing general environmental benefit claims, the Commission's relevant consumer perception study findings, and the Commission's proposed, revised guidance for such claims.

2. Comments

As discussed below, many commenters asserted that general environmental benefit claims may confuse consumers and that the Commission should provide additional guidance on use of these claims, including what type of substantiation supports them and how marketers can effectively qualify them. Other commenters asserted that the Green Guides should prohibit general environmental claims altogether.

a. Substantiating General Environmental Benefit Claims – Life Cycle Considerations

Several commenters recommended that the Guides state that marketers making a general environmental claim have substantiation about the environmental impact of a product throughout its entire life cycle (*see* Part IV.F, *supra*, for a general discussion of comments regarding life cycle

⁹⁰ See, *e.g.*, GPI, Comment 534743-00026 at 10 (citing 16 CFR 260.5).

⁹¹ ACC, Comment 536013-00030 at 4; NatureWorks, Green Packaging Workshop Tr. at 217-18; *see also* Georgia-Pacific, Comment 533431-00007 at 7 (noting that the Guides should provide that claims based on LCA studies be conducted with the full analysis required by ISO 14044); P&G, Comment 533431-00070 at 2 ("While not all claims require a full LCA, recognizing acceptable international standards for LCA will help ensure consistency in claims that do rely upon LCAs for substantiation."); SPI, Comment 533431-00036 at 12 (stating that the scope of the LCA may differ from advertiser to advertiser); USGBC, Comment 536013-00029 at 10-11 (suggesting that if the FTC addresses LCA, it should adopt a particular LCA approach, such as the National Renewable Energy Laboratory's Life Cycle Inventory Database Project, or set forth specific LCA parameters that standardize the relevant impact categories, life cycle stages, and service periods that are the basis of these assessments).

⁹² The Commission did not test consumer perception of life cycle claims in marketing, *i.e.*, claims in which the environmental impacts of a product throughout a product's life cycle are featured in an advertisement or label. The University of Minnesota submitted a study that examined life cycle-based information in marketing. This study, however, focused on consumer perceptions toward the advertiser and the brand, as well as "message credibility," rather than consumer understanding of environmental claims. Comment 536013-00004 at 1.

⁹³ Taking an average across all 15 tested claims (net of control), only nine percent of respondents indicated they thought of all four stages of a product's life cycle when viewing a claim.

⁹⁴ Footnote 2 of the Guides currently states that the Guides do not address LCA claims. 16 CFR 260.7 n.2. The Guides also do not address other environmental claims, but they do not specifically identify these claims. For consistency, the Commission proposes deleting this footnote.

⁹⁵ 16 CFR 260.7(a).

⁹⁶ *Id.*

analysis).⁹⁷ For example, Unilever United States, Inc. asserted that marketers should review all aspects of the product's life cycle to substantiate "eco-friendly" claims because consumers reasonably interpret those claims to mean that the product as a whole offers a material environmental benefit and presents no significant environmental risk.⁹⁸ Similarly, EPA's Sustainable Products Network ("EPA-SPN") asserted that "general claims that imply overall superiority in environmental performance must be substantiated by information that addresses multiple environmental attributes over the product's life cycle."⁹⁹

Although these commenters agreed about the importance of considering a product over its life cycle, they advocated different types and levels of substantiation. Unilever, for example, suggested that the FTC develop criteria under which marketers would have to address the major stages of a product's life cycle – its production, packaging, formula/ingredients, and disposability.¹⁰⁰ Under Unilever's framework, if a company can meet eligibility standards for three out of these four criteria, it could still make a general environmental benefit claim as long as that unmet criterion is clearly and accurately disclosed (*e.g.*, "environmentally friendly, but not recyclable").

EPA-SPN stated that a full quantitative life cycle assessment, "while highly desirable," is not necessary. Instead, marketers should demonstrate that they have addressed "key attributes" from a life cycle perspective.¹⁰¹ Georgia-Pacific also

suggested that the FTC "recognize the use of the ISO 14040 series standards when comparing products and, in particular, the need to include the life cycle impact assessment phase of the LCA as one essential requirement in . . . comparing products."¹⁰²

Several other commenters, however, argued that the FTC should not require marketers making general environmental claims to conduct a full LCA. According to the Business and Institutional Furniture Manufacturer's Association, while conducting an LCA is "an admirable aspiration," the science concerning LCA is not sufficiently well established to mandate such a requirement.¹⁰³ Similarly, the Formaldehyde Council, Inc. asserted that there is a debate regarding how various factors used in life cycle assessment are weighted in developing an overall assessment.¹⁰⁴ Other commenters similarly argued that life cycle assessment should not be the only tool available to marketers to substantiate general environmental claims, explaining that LCAs are complex, difficult to interpret, and costly.¹⁰⁵ Therefore, commenters noted that conducting an LCA may not be feasible even for large companies.¹⁰⁶

b. Qualifying General Environmental Benefit Claims

Some commenters recommended that the Guides provide additional advice on how marketers can effectively qualify

14024 standard for Type 1 environmental labels; or 3) life cycle analyses that follow the requirements of the ISO 14040-series of standards for life cycle assessment." EPA-SPN, Comment 536013-00062 at 11; *see also* EPA-EPPP, Comment 533431-00038 at 6.

⁹⁷ Georgia-Pacific, Comment 533431-00007 at 3.

⁹⁸ BIFMA, Green Building and Textiles Workshop Tr. at 246; Sophia Greenbaum, Sustainable Buildings Industry Council ("SBIC"), Green Building and Textiles Workshop Tr. at 246 (suggesting that there is no single methodology for establishing life cycle analysis); *see also* Green Seal, Green Building and Textiles Workshop Tr. at 247.

⁹⁹ Formaldehyde Council, Inc., Comment 533431-00047 at 3.

¹⁰⁰ SDA, Comment 534734-00028 at 3 (stating the FTC should not require an LCA as substantiation for "properly qualified, well-supported claims" due to the cost such a requirement would impose on small businesses, but that the Guides, nevertheless, should encourage marketers to conduct a "sufficient inquiry to avoid the use of claims . . . that do not acknowledge other significant environmental impacts associated with a product's formulation process or its use"); The Clorox Company ("Clorox"), Comment 534743-00017 at 1 (asserting that even when marketers are making general claims, they should not be required to conduct a life cycle assessment); *see also* ACC, Comment 533431-00023 at 5 (stating that LCA studies should not be a necessary precondition to making an environmental claim).

¹⁰¹ Estée Lauder, Green Packaging Workshop Tr. at 176; Michigan State Univ., Green Packaging Workshop Tr. at 161.

general environmental benefits. For example, one commenter suggested that the Guides should advise marketers on how to use more effective qualifiers. This commenter specifically advised the Commission to require that qualifications be "clear, understandable, prominently displayed, and indicate an actual environmental benefit."¹⁰⁷ This commenter also emphasized that a consumer evaluating an advertisement should be able to "quickly and easily tell that the environmental benefit that the product has is the specific environmental benefit indicated, not the wider general benefit included in the ad's message – *i.e.*, by such phrases as 'environmentally friendly.'"¹⁰⁸ Another commenter asserted that the FTC should provide examples of accompanying language that would be specific enough to allow the use of these types of claims.¹⁰⁹

c. Prohibiting All General Environmental Benefit Claims

Some commenters argued that by allowing general environmental benefit claims, even when qualified, the Guides facilitate deception.¹¹⁰ These commenters, therefore, recommended that the Green Guides prohibit all general environmental claims. For example, GreenBlue argued that there is no single definition of general environmental benefit terms such as "green" or "environmentally friendly." Therefore, their use only confuses consumers even if the terms are qualified with text that describes the specific attribute that contributes to their "green" status.¹¹¹ GreenBlue noted that "environmental excellence" in one attribute can result in trade-offs in another. For example, the increased use of recycled content may require less energy for material production, but may result in greater weight and, therefore, higher energy costs for transportation.

¹⁰⁷ Krenn, Comment 533431-00014 at 5.

¹⁰⁸ *Id.*

¹⁰⁹ 3M Company, Comment 533431-00027 at 3; *see also* EHS, Comment 533431-00057 at 2 (suggesting that general claims should never appear without a clear statement of the product's specific attributes and that "sufficient point of sale information should be made available to the consumer as to what the environmentally preferred attributes are").

¹¹⁰ Banning general environmental benefit claims would be consistent with ISO 14021, which prohibits general environmental claims. Specifically, ISO 14021 provides that "[a]n environmental claim that is vague or non-specific or which broadly implies that a product is environmentally beneficial or environmentally benign shall not be used. Therefore, environmental claims such as 'environmentally safe,' 'environmentally friendly,' 'earth friendly,' 'non-polluting,' 'green,' 'nature's friend,' and 'ozone friendly' shall not be used." ISO 14021 5.3:1999(E).

¹¹¹ GreenBlue, Comment 533431-00058 at 4-5.

⁹⁷ *See, e.g.*, Michigan State Univ., Green Packaging Workshop Tr. at 187 ("[I]t is precisely those broad claims that should never be made unless you can back them up and the only way you could back them up would be with a full blown life cycle analysis."); Keith Christman, American Chemistry Council ("ACC"), Green Packaging Workshop Tr. at 210; GPI, Comment 534743-00026 at 9-10.

⁹⁸ Unilever United States, Inc. ("Unilever"), Comment 534743-00030 at 1.

⁹⁹ EPA-SPN, Comment 536013-00062 at 4; *see also* P&G, Comment 533431-00070 at 3 (stating that in the absence of a life cycle analysis, comparative environmental claims should be limited to specific and verifiable parameters regarding the sourcing of raw materials, manufacturing, transportation, or packaging); Georgia-Pacific, Comment 533431-00007 at 3.

¹⁰⁰ Unilever, Comment 534743-00030 at 1-2.

¹⁰¹ Specifically, EPA-SPN recommended that the following types of information provide "adequate substantiation" for general environmental benefit claims: "1) certification under voluntary consensus standards that include multiple environmental attributes based on consideration of the product's life cycle; 2) certification under multi-attribute, life cycle-based eco-labeling programs, such as labeling programs that follow the requirements of the ISO

According to GreenBlue, because such trade-offs are sufficiently common, the Guides should discourage general environmental benefit claims, even when accompanied by a specific-attribute qualifier, unless a company is willing to include a full explanation of environmental trade-offs.

Similarly, EPA-SPN provided an example of a potentially deceptive qualified claim. It noted that a product advertised as “Eco-safe because of low-VOC content” implies that VOC content is the most important factor in determining “overall environmental performance.” EPA-SPN cautioned that it is not possible to know if this is actually the case without information on other product attributes. EPA-SPN, therefore, suggested that marketers “state the claim in terms of the relevant attribute without implying broader environmental benefit, e.g., “100% post-consumer content” or “low VOC.” EPA-SPN also recommended that any further description be limited to a statement of environmental benefit directly related to the attribute. Thus, according to EPA-SPN, a claim such as “Low VOC – promotes cleaner air” would be proper because “VOC emissions have a clear relationship to air quality.”¹¹²

3. Consumer Perception Evidence

Only a few commenters submitted consumer perception evidence addressing general environmental benefit claims.¹¹³ Thus, the Commission’s study focused on this issue. The study examined whether both unqualified and qualified general green claims suggested that the product has particular environmental benefits. Specifically, the study asked respondents whether these types of claims conveyed that the product had any of the following seven environmental attributes: made from

recycled materials, made with renewable materials, recyclable, made with renewable energy, biodegradable, non-toxic, and compostable. Thus, for example, would consumers viewing a “green” or an “eco-friendly” claim think that the advertised product had specific green attributes, such as being made with recycled materials or being recyclable? Additionally, if the general green claim were qualified with a specific environmental attribute, such as “green - made with renewable materials,” would consumers think the product had environmental benefits beyond the specific attribute mentioned?¹¹⁴

Averaging across the seven attributes, 52 percent of respondents viewing an unqualified “green” claim indicated that they believed that the product had a specific attribute about which the survey asked. In particular, responses for individual attributes ranged from 61 percent (product is made from recycled materials) to 40 percent (product is compostable). The responses concerning an unqualified “eco-friendly” claim were similar. Averaging across the seven attributes, 49 percent indicated that the claim suggested that the product had a particular attribute. Specifically, responses for individual attributes ranged from 56 percent (product is made from recycled materials) to 36 percent (product is made with renewable energy). When the general environmental claims were qualified, however, on average, 31 percent of consumers indicated that the claim implied specific environmental benefits in addition to the attribute stated.¹¹⁵

In addition to asking consumers about unqualified and qualified-general environmental benefit claims, the study asked consumers how they perceive certain specific-attribute claims alone (*i.e.*, claims that a product is “made with recycled materials,” “made with renewable materials,” or “made with renewable energy”). This allowed the Commission to compare qualified-general claims to specific-attribute claims to determine the extent to which the general environmental claim (*e.g.*,

“green,” “eco-friendly”) contributed to consumer perceptions. On average, 23 percent of respondents viewing specific-attribute claims indicated that the claim implied specific benefits in addition to the attribute stated.

The study further examined whether consumers believe that environmental claims suggest anything about any negative environmental impact that may come from the product. Twenty-seven percent of respondents interpreted the unqualified claims “green” and “eco-friendly” as suggesting the product has no negative environmental impact.¹¹⁶ Sixteen percent of respondents viewing a qualified “green” claim and 17 percent of those viewing a qualified “eco-friendly” claim made the same inference, while only ten percent of respondents viewing a specific-attribute claim made this inference.

4. Analysis and Guidance

Both the comments¹¹⁷ and FTC staff’s Internet surf¹¹⁸ indicate that general environmental claims are pervasive. Such general claims appear both alone¹¹⁹ and accompanied by specific claims.¹²⁰ To address their potential for consumer deception, and based on the comments and the Commission’s consumer perception study, the Commission proposes advising marketers not to make unqualified general environmental benefit claims.¹²¹ The proposed, revised Guides also provide more prominent guidance on how to effectively qualify general environmental benefit claims.

¹¹⁶ This figure is based on the responses to a closed-ended question on what “green” or “eco-friendly” claims suggest or imply about any negative environmental impact resulting from the tested products. Responses to subsequent questions suggest that respondents were not all thinking about negative environmental impact in exactly the same way in answering this question.

¹¹⁷ See, e.g., ACC, Comment 533431-00023 at 6; Clorox, Comment 534743-00017 at 1; 3M Company, Comment 533431-00027 at 3; Krenn, Comment 533431-00014 at 2; TerraChoice, Comment 533431-00040 at 3.

¹¹⁸ In December 2008, FTC staff conducted a review of Internet sites to investigate the nature and incidence of certain environmental marketing claims. See Green Marketing Internet Surf, A Report by the FTC’s Division of Enforcement (“FTC Staff Internet Surf”).

¹¹⁹ In the FTC Staff Internet Surf, an express “green” claim occurred in 49 percent of the 799 web pages containing general environmental claims, and eco-/earth-/environmentally “friendly” occurred in 41 percent of them.

¹²⁰ For example, in the FTC Staff Internet Surf, on the 799 web pages with general environmental claims, renewability claims co-occurred on 36 percent of the pages; carbon claims co-occurred on 35 percent of them; recycled content claims co-occurred on 18 percent; and biodegradability claims co-occurred on 12 percent.

¹²¹ This proposed guidance can be found in 16 CFR 260.4.

¹¹² EPA-SPN, Comment 536013-00062 at 4-5; see also EPI, Comment 533431-00063 at 4 (suggesting that the Commission revise the Guides to make clear that information about specific product attributes will not necessarily qualify general environmental claims); Rebekah Lacey (“Lacey”), Comment 533431-00062 at 2 (“Manufacturers . . . should not be able to pick and choose the criteria they use to make general environmental benefit claims. Even if they disclose the criteria, they are still implying that the criteria are appropriate, which is inherently misleading if the criteria focus on a narrow aspect of the product’s life cycle environmental impact.”); USGBC, Comment 536013-00029 at 9 (noting that qualifying broad environmental claims based on a single product attribute may be misleading because it ignores the full impact of the product on the environment).

¹¹³ See, e.g., Cone LLC, Comment 534743-00007 at 2 (describing its February 2008 online survey of over 1,000 consumers and noting that 48 percent of respondents believed a product marketed as “green” or “environmentally friendly” has a “positive, (*i.e.*, beneficial) impact” on the environment).

¹¹⁴ The Commission tested the following qualified-general claims: “green - made with renewable materials”; “green - made with renewable energy”; “green - made with recycled materials”; “eco-friendly - made with renewable materials”; “eco-friendly - made with renewable energy”; and “eco-friendly - made with recycled materials.”

¹¹⁵ This figure was derived by calculating an average of responses regarding six qualified-general claims (three of which qualified “green”; three of which qualified “eco-friendly”). When participants were asked to evaluate a claim that included one of the specific-attribute claims, such as “green - made with renewable materials,” we did not include responses regarding that attribute (“made with renewable materials”) in that calculation.

a. Unqualified General Environmental Benefit Claims

The consumer perception evidence and some comments reaffirm the current Guides' advice that unqualified general environmental benefit claims convey a range of meanings. For example, the Commission's consumer perception study found that 61 percent of respondents viewing an unqualified "green" claim believed the product is made from recycled materials; 59 percent believed the product is recyclable; 54 percent believed the product is made with renewable materials; 53 percent believed the product is biodegradable; 48 percent believed the product is made with renewable energy; 45 percent believed the product is non-toxic; and 40 percent believed the product is compostable.¹²² Averaging across these seven attributes, 52 percent of respondents viewing an unqualified "green" claim stated that the claim definitely or probably suggested that the product had these specific green attributes. The percentages are similar for respondents viewing an "eco-friendly" claim.¹²³ Moreover, 27 percent of respondents interpreted the unqualified claims "green" and "eco-friendly" as suggesting the product has no negative environmental impact.

Given these findings, and because FTC law requires marketers to substantiate every express and implied environmental benefit that consumers reasonably could take from such a claim,¹²⁴ unqualified general environmental marketing claims remain very difficult, if not impossible, to substantiate. Very few products, if any, have all of the attributes consumers appear to perceive from general environmental benefit claims. In addition, given that all products have some environmental impact, it is doubtful that a marketer could

substantiate that a product has no or negligible negative environmental impact. The Commission, therefore, proposes revising the Guides to more directly caution marketers not to make unqualified general environmental benefit claims.

Because marketers should not make unqualified general environmental benefit claims, the Commission declines to adopt commenters' suggestions that the Guides delineate the particular substantiation needed to support such claims. Moreover, unlike the approach taken by ISO 14021, which prohibits general environmental claims, the Commission does not propose advising marketers to never use a general environmental benefit claim. As discussed below, marketers may be able to effectively qualify these claims to focus consumers on the specific environmental benefits that marketers could substantiate.

b. Qualified General Environmental Benefit Claims

The current Guides state that marketers may make broad environmental claims if they are "qualified, as necessary, to prevent deception about the specific nature of the environmental benefit being asserted."¹²⁵ Through examples, the Guides also advise marketers that qualifications should be sufficiently "clear and prominent" to convey the idea that the claim refers only to limited environmental benefits and that "no other deceptive implications are created by the context." The Commission's consumer perception study supports this advice by demonstrating that qualifying a general green claim reduces the number of respondents believing: (1) that a product has specific, unstated benefits; and (2) that a product has no negative environmental impact.

First, as discussed above, on average, approximately half of the respondents viewing a general, unqualified "green" claim believed that the claim suggested specific, unstated environmental benefits. When viewing a qualified "green" claim, on average, substantially fewer consumers (30 percent) believed that the claim suggested specific, unstated benefits.¹²⁶ For example, when

a "green" claim was qualified with the statement "made with recycled materials," 26 percent of respondents took away implied claims, a decrease of 26 percentage points. Similarly, when a "green" claim was qualified with the statement "made with renewable energy," 29 percent of respondents took away implied claims, a decrease of 22 percentage points.

Second, the survey results indicate that the qualification of a general claim reduces consumer misperception of a product's overall environmental impact. While 27 percent of respondents stated that a product advertised with an unqualified "green" or "eco-friendly" claim had no environmental impact, only 16 percent of respondents viewing a qualified "green" claim, and 17 percent of those viewing a qualified "eco-friendly" claim, made the same inference.

Although the percentage of respondents believing that a product had specific, unstated benefits and had no negative impact significantly decreased, some respondents still saw implied claims. Specifically, 31 percent of respondents saw implied claims, and 17 percent believed a product had no negative impact. To determine the extent to which the general environmental claim (e.g., "green," "eco-friendly") contributed to these continuing perceptions, the Commission compared qualified-general claims to specific-attribute claims alone (e.g., "made with recycled materials"). Respondents viewing qualified-general claims were only eight percent more likely to see implied claims than those viewing the specific-attribute only claims.¹²⁷ Moreover, respondents viewing qualified-general claims were only approximately six percent more likely to state that the product had no negative environmental impact than those viewing specific-attribute claims alone.¹²⁸ Thus, when qualified, the use of a general green claim did not appear to significantly contribute to consumers' propensity to see implied claims or to believe a product had no negative environmental impact.

The results, therefore, suggest that qualifying a general environmental claim can focus consumers on the specific advertised benefit and significantly reduce misperceptions

¹²² As discussed above, the Commission tested the claims as they appeared on laundry baskets, kitchen flooring, and wrapping paper. The response rates for laundry baskets and kitchen flooring were very similar. A slightly larger percentage of respondents perceived wrapping paper to possess unstated environmental attributes. However, because the responses were interpreted net of a non-environmental control claim, the analysis largely eliminated this difference from the results.

¹²³ Of respondents viewing an "eco-friendly" claim, 57 percent believed the product is recyclable; 56 percent believed the product is made from recycled materials; 55 percent believed it is biodegradable; 51 percent believed it is made with renewable materials; 47 percent believed it is non-toxic; 43 percent believed it is compostable; and 36 percent believed it is made with renewable energy. The average value was 49 percent.

¹²⁴ FTC Policy Statement Regarding Advertising Substantiation ("Substantiation Policy Statement"), appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

¹²⁵ 16 CFR 260.7(a).

¹²⁶ To calculate this number, the Commission took an average across all three qualified- "green" claims: "green - made with renewable materials"; "green - made with renewable energy"; and "green - made with recycled materials." The results are similar for qualified "eco-friendly" claims, where, on average, 32 percent of participants took away the specific, unstated attributes, compared to the 49 percent who took away specific, unstated attributes when presented with the unqualified "eco-friendly" claim.

¹²⁷ On average, 31 percent of consumers viewing qualified-general claims and 23 percent of consumers viewing specific-attribute claims saw implied claims.

¹²⁸ On average, approximately 16 percent of consumers viewing qualified-general claims and 10 percent of consumers viewing specific-attribute claims believed the claims implied no negative environmental impact.

about negative environmental impact. Based on these findings, the Commission proposes to emphasize the current Guides' advice on qualifying general environmental benefit claims. The proposed, revised section states that marketers must use clear and prominent qualifying language to convey to consumers that a general environmental claim refers only to a specific and limited environmental benefit. The section also cautions marketers that explanations of specific attributes, even when true and substantiated, will not adequately qualify a general environmental marketing claim if the advertisement's context implies other deceptive claims. Therefore, the proposed Guides remind marketers they should ensure that the advertising's context creates no deceptive implications.

Marketers also should use caution with qualifications to ensure that they are not making additional claims they cannot substantiate. The Commission's study demonstrates that even some specific-attribute claims caused consumers to believe the advertised product had other, unstated environmental attributes. For example, 30 percent of respondents viewing a "made with renewable materials" claim believed the advertised product had environmental attributes not expressly mentioned in the claims. Therefore, marketers must substantiate additional claims conveyed by the qualification itself.

Determining whether a general environmental claim is adequately qualified depends heavily on the claim's context.¹²⁹ To provide additional guidance on this point, the Commission proposes adding a new example to the Guides. In proposed Example 3, the marketer's claim that its packaging is now "Greener than our previous packaging" is likely deceptive even

¹²⁹ In determining if reasonable consumers are likely to take an implied claim, the Commission looks at the net impression created by the advertisement as a whole. Deception Policy Statement, 103 F.T.C. at 179. Example 2 in the current and proposed Guides presents a scenario in which the context of the claim creates "deceptive implications." 16 CFR 260.7(a), Example 2. In this example, a product wrapper is printed with the claim "environmentally friendly." Text on the wrapper explains that the wrapper is environmentally friendly because it was "not chlorine bleached, a process that has been shown to create harmful substances." Although the wrapper was not bleached with chlorine, its production releases other harmful substances. Since consumers are likely to interpret the "environmentally friendly" claim, *in combination with the textual explanation*, to mean that no significant harmful substances are currently released into the environment, the "environmentally friendly" claim would be deceptive.

though the marketer reduced the weight of its packaging, compared to previous packaging, by 15 percent. The example notes that consumers likely interpret "Greener" in this context to mean that other significant environmental aspects of the packaging have been improved. Proposed Example 3 suggests that the marketer qualify the claim by clearly stating that it reduced the weight of its packaging, compared to previous packaging, by 15 percent. If the advertisement's context does not imply other deceptive claims, this claim likely would not be deceptive.

The Commission is concerned that a general environmental benefit claim, in combination with a particular attribute, may imply that the particular attribute provides the product with a net environmental benefit. If a particular attribute represents an environmental improvement in one area, but causes a negative impact elsewhere that makes the product less environmentally beneficial than the product otherwise would be, consumers may be misled. For example, a marketer that claims its product is "Green – Now contains 70 percent recycled content," needs to import more materials from a distant source, resulting in increased energy use which more than offsets the environmental benefit achieved by using recycled content. If consumers interpret the claim "Green – Now contains 70 percent recycled content" to mean that the product has a net environmental benefit, the claim would be deceptive. The Commission, therefore, requests comment on consumer interpretation of qualified-general environmental benefit claims and on whether to include guidance concerning this issue.

The following part on certifications and seals further discusses the issue of broad, unqualified green claims and includes additional examples of effective qualifications.

B. Certifications and Seals of Approval

1. The Current Guides

Currently, the Guides do not contain a section devoted to certifications and seals of approval. However, one example notes that an environmental seal of approval ("seal") may imply that a product is environmentally superior to other products. Specifically, Example 5 in the general environmental benefit claims section provides: "A product label contains an environmental seal, either in the form of a globe icon, or a globe icon with only the text 'Earth Smart' around it. Either label is likely to convey to consumers that the product is environmentally superior to other

products. If the manufacturer cannot substantiate this broad claim, the claim would be deceptive."¹³⁰ Accordingly, the Guides instruct marketers who use environmental seals to accompany such claims with clear and prominent language limiting any environmental superiority representation to the particular product attribute or attributes it can substantiate.¹³¹

2. Comments

Several commenters and panelists identified the use of third-party certifications as a significant green marketing trend¹³² and highlighted the benefits of such certifications to businesses and consumers.¹³³ For example, Green Seal, Inc. asserted that third-party certification provides marketers with independent and credible substantiation.¹³⁴ Weyerhaeuser stated that third-party certifications are "useful in technical areas, where consumers face difficulty in understanding or directly measuring benefits."¹³⁵ Similarly, the U.S. Green Building Council observed that "when properly administered by certifying organizations truly independent of the product manufacturer and appropriately represented by marketers, . . . third-party certification takes the guesswork out of consumer purchases, providing an independent and expert assessment of

¹³⁰ 16 CFR 260.7(a), Example 5.

¹³¹ *Id.* FTC staff's brochure for businesses, "Complying with the Environmental Marketing Guides," ("FTC Staff's Business Brochure") reiterates this guidance and states that third-party certification does not insulate an advertiser from Commission scrutiny or eliminate an advertiser's obligation to ensure that it has substantiation for the claims communicated by the certification. In addition, the FTC Staff's Business Brochure advises that if a seal of approval "implies that a third party has certified the product, the certifying party must be truly independent from the advertiser and must have professional expertise in the area that is being certified." FTC Staff's Business Brochure, *Complying with the Environmental Marketing Guides* at 6, available at (<http://www.ftc.gov/bcp/edu/pubs/business/energy/bus42.pdf>).

¹³² *See, e.g.*, Weyerhaeuser, Comment 534743-00033 at 2 ("The emergence of environmental seals and third-party certifications is one of the most important trends the FTC identified as posing potential problems for consumers."); AF&PA, Comment 534743-00031 at 2; David Mallen, National Advertising Division, CBDB ("NAD"), Green Packaging Workshop Tr. at 46; USGBC, Comment 534743-00027 at 3.

¹³³ *See, e.g.*, USGBC, Comment 536013-00029 at 3-4 (noting that rating systems provide a consistent and quantifiable definition of "green building" for consumers and an expert, third-party assurance that technical claims are true); Clorox, Comment 534743-00017 at 1.

¹³⁴ Green Seal, Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/baldwin.pdf>).

¹³⁵ Weyerhaeuser, Comment 534743-00033 at 2; *see also* Clorox, Comment 534743-00017 at 1; Formaldehyde Council, Comment 533431-00047 at 6.

technical product claims that may be difficult for consumers to interpret or verify on their own.¹³⁶ Cone LLC affirmed that consumers rely on certifications when evaluating environmental claims. Its opinion survey found that 80 percent of respondents believed that certification by third-party organizations is “important in providing oversight to ensure environmental messaging by companies is accurate.”¹³⁷

One commenter, however, noted that consumers typically cannot verify third-party certifications. Therefore, there is a “heightened degree of trust involved, and there is a heightened degree of credibility that is at stake.”¹³⁸ Other commenters cautioned that seals and logos may communicate a general claim of environmental preferability with no means for the consumer to determine which environmental benefits form the basis for the claim.¹³⁹

Notwithstanding the benefits of third-party certifications, several panelists and commenters highlighted areas of potential consumer confusion and made various suggestions regarding how to address that confusion. The following discusses commenters’ suggestions addressing the use of certifications and seals in marketing and when third-party certifications adequately substantiate environmental claims.

a. Use of Certifications and Seals in Marketing

Several panelists and commenters suggested that the FTC provide additional guidance on when the display of certifications and seals is likely to mislead consumers.¹⁴⁰ For example, one commenter asserted that seals of approval and “eco-labels” “that communicate a general ‘environmentally friendly’ message to consumers should be treated as environmental claims within the scope of the guides and be subject to

applicable principles and criteria.”¹⁴¹ This commenter suggested that the FTC more prominently feature its advice on the need to qualify certain types of seals that could connote general environmental benefits.¹⁴² Another commenter suggested that marketers generally should not use “vague, undefined” environmental terms but should be able to incorporate such terms into certifications, as long as the marketer makes the method and terms of the certification publicly available and easily accessible.¹⁴³

Several commenters recommended that the Guides include examples illustrating ways in which marketers could effectively qualify third-party certifications and seals of approval.¹⁴⁴ In the building context, for example, commenters suggested the Guides include examples illustrating how marketers can qualify certifications to distinguish between building design features and performance and to clarify whether a certification applies to a product or whole building.¹⁴⁵

Commenters also recommended that the Guides address how marketers can avoid misleading consumers about the certifier’s independence.¹⁴⁶ For example, one commenter opined that self-certifications “can be misleading to consumers unless the company expressly discloses that the certification has not been conducted by an independent third-party.”¹⁴⁷ Another asserted that the Guides should address the financial relationship between the

certifying organization and the company being certified.¹⁴⁸

In addition, commenters addressed how marketers can avoid misleading consumers about the basis for a certification. For example, because consumers may confuse a logo that simply indicates membership in an organization with one that certifies an aspect of a product’s environmental performance, a commenter recommended that marketers distinguish between the two.¹⁴⁹ Other commenters suggested that the FTC provide guidance to help avoid confusion about certifications that falsely appear to be bestowed by a government agency.¹⁵⁰ Finally, commenters observed that certification programs may address some, but not all, aspects of a product.¹⁵¹ Therefore, they recommended guidance cautioning marketers not to indicate approval of an environmental attribute that the certifier did not evaluate.¹⁵²

b. Third-Party Certifications as Substantiation

Commenters also advised the FTC to address the use of third-party certifications to substantiate claims. Several urged the Commission not to require third-party certification as substantiation for an environmental claim.¹⁵³ Others recommended that the FTC revise the Guides to set forth the parameters of a third-party certification that would constitute adequate substantiation.¹⁵⁴ Some commenters

¹⁴⁸ Skye Con, Comment 536013-00036 at 3.

¹⁴⁹ SBIC, Green Building and Textile Workshop Tr. at 224; *see also* Gensler, Green Building and Textile Workshop Tr. at 135 (stating that marketers need to make sure that graphics do not imply more than is actually being delivered); OMI, Comment 536013-00022 at 3 (noting that advertisements must clearly state whether a logo refers to membership only or a “verifiable claim of certification”).

¹⁵⁰ ACC, Comment 536013-00030 at 4; NAIMA, Comment 536013-00017 at 8.

¹⁵¹ USGBC, Comment 534743-00027 at 4; *see also* SDA, Comment 534743-00028 at 3.

¹⁵² USGBC, Comment 534743-00027 at 4.

¹⁵³ ATA, Comment 533431-00041 at 8 (stating that requiring third-party certification to substantiate claims “would impose unnecessary and impractical burdens on advertisers” and that those claims may already be adequately substantiated under the FTC Act); AF&PA, Comment 533431-00019 at 2; Sappi Fine Paper North America (“Sappi”), Comment 534743-00023 at 2; Skye Con, Comment 536013-00036 at 3; The Vinyl Institute (“Vinyl Institute”), Comment 533431-00046 at 4. *But see* Healey, Comment 533431-00048 at 7 (stating that FTC could prohibit broad claims unless they are certified by an independent party); Patagonia, Inc. (“Patagonia”), Comment 536013-00011 at 1 (noting that marketers making “safer” chemical use or water/energy conservation claims in textiles should substantiate claims with third-party certifications).

¹⁵⁴ *See, e.g.*, ACC, Comment 536013-00030 at 3-4; AF&PA, Comment 536013-00021 at 2-3; AZS

¹³⁶ USGBC, Comment 534753-00027 at 3.

¹³⁷ Cone LLC, Comment 534743-00007 at 9; *see also* Tandus, Comment 536013-00037 at 1 (“[I]ndependent, third party verification and certification provides extra credibility and assurance that the manufacturers’ claims are truthful and accurate.”).

¹³⁸ NAD, Green Packaging Workshop Tr. at 46.

¹³⁹ CSPA, Comment 533431-00049 at 2-3; P&G, Comment 533431-00070 at 2; SDA, Comment 536013-00018 at 2; USGBC, Comment 536013-00029 at 6; Saint-Gobain, Comment 533431-00037 at 7-8.

¹⁴⁰ *See, e.g.*, ACC, Comment 536013-00030 at 3-4; CSPA, Comment 533431-00049 at 2-3; Johns Manville, Comment 536013-00034 at 6; Michelle Moore, USGBC, Green Building and Textiles Workshop Tr. at 197; SBIC, Green Building and Textiles Workshop Tr. at 224; SPI, Comment 533431-00036 at 11; USGBC, Comment 536013-00029 at 3.

¹⁴¹ P&G, Comment 533431-00070 at 2; *see also* USGBC, Comment 536013-00029 at 6 (stating that marketers should specify the attributes to which a seal refers in order to help consumers interpret their meaning); CSPA, Comment 533431-00049 at 3; Saint-Gobain, Comment 533431-00037 at 3.

¹⁴² P&G, Comment 533431-00070 at 2; *see* 16 CFR 260.7(a), Example 5.

¹⁴³ Greenpeace USA, Comment 536013-00020 at 3.

¹⁴⁴ *See, e.g.*, GMA, Comment 533431-00045 at 4; SPI, Comment 533431-00036 at 8-9.

¹⁴⁵ *See, e.g.*, ACC, Comment 536013-00030 at 1; Johns Manville, Comment 536013-00034 at 6; USGBC, Comment 536013-00029 at 4-5.

¹⁴⁶ ACC, Comment 536013-00030 at 3 (noting that marketers should distinguish seals based on voluntary consensus standards from other certifications and that the FTC should aid consumers in distinguishing among certification programs, including those that use life cycle assessment as the basis for certification); Frank Hurd, CRI (“CRI”), Green Building and Textile Workshop Tr. at 153; Johns Manville, Comment 536013-00034 at 7-8; NAIMA, Comment 536013-00017 at 9; USGBC, Comment 536013-00029 at 2-3.

¹⁴⁷ CRS, Comment 534743-00009 at 4-5; *see also* Gensler, Green Building and Textiles Workshop Tr. at 109 (highlighting the differences between self-certification; certification where there is a relationship between the certifying organization and marketer – *e.g.*, marketer is a member of the certifying trade association; and certification by an independent third-party).

and panelists stated that marketers relying on a third-party certification as substantiation must be able to show that the certifying party is truly independent from the advertiser and that the certifying party has professional expertise in the area that is being certified.¹⁵⁵ Thus, for example, some commenters proposed that the Guides reiterate, or at least cross-reference, the principles outlined in the Guides Concerning the Use of Endorsements and Testimonials in Advertising (“Endorsement Guides”),¹⁵⁶ including that endorsements may not contain factual representations that would be deceptive or could not be substantiated if made directly by the advertiser¹⁵⁷ and that marketers should not rely on endorsements by entities that have a monetary or other relationship with the marketer.¹⁵⁸

Panelists and commenters also suggested the Guides provide that third-party certification programs be developed through an open, transparent and balanced process, such as programs accredited through the American National Standards Institute (“ANSI”).¹⁵⁹ Other commenters, however, observed that achieving openness and balance is difficult because not all parties may be given a voice in the proceedings, and those making the decisions on the standard may possess ideological views adverse to certain interests.¹⁶⁰

Consulting, Inc., Comment 536013-00024 at 1-2; Healey, Comment 533431-00048 at 2; Johns Manville, Comment 536013-00034 at 6; SDA, Comment 536013-00018 at 2; Skye Con, Comment 536013-00036 at 3; SPI, Comment 533431-00036 at 12; USGBC, Comment 536013-00029 at 4; Vinyl Institute, Comment 536013-00019 at 2-3; Weyerhaeuser, Comment 536013-00035 at 2.

¹⁵⁵ See, e.g., GMA, Comment 533431-00045 at 6; *see also* Todd Copeland, Patagonia, Inc. (“Patagonia”), Green Building and Textiles Workshop Tr. at 81-82; EConscious, Comment 536013-00023 at 1-2; Grace Gershuny, Organic Trade Association (“OTA”), Green Building and Textiles Workshop Tr. at 62; Oeko-Tex Certification Body (USA) (“Oeko-Tex”), Comment 536013-00013 at 4; Skye Con, Comment 536013-00036 at 3.

¹⁵⁶ 16 CFR Part 255.

¹⁵⁷ GMA, Comment 533431-00045 at 6; Johns Manville, Comment 536013-00034 at 6; Cassie Phillips, Weyerhaeuser (“Weyerhaeuser”), Green Packaging Workshop Tr. at 220-221; Weyerhaeuser, Comment 534743-00033 at 2.

¹⁵⁸ AF&PA, Comment 534743-00031 at 2; *see also* CRS, Comment 534743-00009 at 4 (stating that because consumers assume certifications have been conducted by independent third-parties, companies should expressly disclose when they have not); AF&PA, Comment 534743-00031 at 2; Green Seal, Green Packaging Workshop Tr. at 199-200; Healey, Comment 533431-00048 at 8.

¹⁵⁹ USGBC, Green Building and Textile Workshop Tr. at 134,160-61; USGBC, Comment 536013-00029 at 5; *see also* Oeko-Tex, Comment 536013-00013 at 6.

¹⁶⁰ Vinyl Institute, Comment 536013-00019 at 2; *see also* ECM Biofilms, Inc. (“ECM Biofilms”),

In lieu of delineating general parameters, some panelists and commenters urged the FTC to establish particular standards that, for example, would establish a certification system.¹⁶¹ Others, however, asserted this should not be the FTC’s role.¹⁶²

3. Analysis and Guidance

Marketers across industry sectors increasingly use certifications and seals of approval to communicate environmental claims. These certifications vary from seals of approval issued by third-parties to logos developed internally pursuant to company-specific standards. Third-party certification programs include certification for single attributes (e.g., “recycled content”) and multiple attributes, which may incorporate environmental considerations throughout the life cycle of the product.

Given the widespread use of certifications and seals and their potential for consumer confusion, the Commission proposes providing additional guidance, specifically in a new Guide section devoted to this subject.¹⁶³ This section emphasizes that third-party certifications and seals constitute endorsements covered by the Endorsement Guides.¹⁶⁴ This section also states that the use of a certification or seal by itself may imply a general environmental benefit claim. Because, as discussed above, such claims are so difficult to substantiate, this section further advises marketers not to use unqualified seals or certifications. Marketers should accompany seals or certifications with clear and prominent language limiting the general environmental benefit claim to the particular attribute or attributes for which they have substantiation. Finally, the section addresses the use of certifications as substantiation.

Comment 534743-00025 at 2 (commenting that to be an active member of ASTM and to author standards takes resources that are not available to many organizations, and “[a]s a result, standards are written to be beneficial to certain organizations”).

¹⁶¹ See, e.g., Builders Association of South Florida, Comment 536013-00010 at 1; Stephen Richard Sides, National Paint and Coatings Association, Inc. (“NPCA”), Green Building and Textiles Workshop Tr. at 128.

¹⁶² See John Girman, EPA, Green Building and Textiles Workshop Tr. at 200-201; Carlos Martin, National Association of Home Builders (“NAHB”), Green Building and Textiles Workshop Tr. at 198-200.

¹⁶³ This proposed guidance can be found in 16 CFR 260.6.

¹⁶⁴ 16 CFR Part 255. The Endorsement Guides provide guidance on the non-deceptive use of endorsements in marketing and outline the parameters of endorsements that would be considered adequate substantiation for marketing claims.

a. Certifications and Seals as Endorsements

The proposed new section advises marketers that it is deceptive to misrepresent, directly or by implication, that a product, package, or service has been endorsed or certified by an independent, third-party organization. The proposed section states that third-party certifications are endorsements,¹⁶⁵ which should meet the criteria for endorsements set forth in the FTC’s Endorsement Guides. In particular, the proposed section advises marketers to review the following Endorsement Guides sections: Definitions,¹⁶⁶ General Considerations,¹⁶⁷ Expert Endorsements,¹⁶⁸ Disclosure of Material Connections,¹⁶⁹ and Endorsements by Organizations.¹⁷⁰

Rather than simply repeating the Endorsement Guides’ text, the proposed Green Guides section provides several examples of how the Endorsement Guides apply in the context of environmental claims. Proposed Example 1 addresses the use of a seal of approval created by the marketer itself, rather than bestowed by a third-party. In this example, the advertisement implies that an independent third-party certifier with appropriate expertise awarded the seal. The example notes that this unqualified claim would be deceptive because consumers would assume that an independent, third-party certifier

¹⁶⁵ The Endorsement Guides define an endorsement as “any advertising message . . . that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.” 16 CFR 255.0.

¹⁶⁶ *Id.*

¹⁶⁷ 16 CFR 255.1. This section provides, among other things, that “[e]ndorsements must reflect the honest opinions, findings, beliefs, or experience of the endorser,” and that the endorsement “may not convey any express or implied representation that would be deceptive if made directly by the advertiser.”

¹⁶⁸ 16 CFR 255.3. An expert endorser is someone who, as a result of experience, study, or training, possesses knowledge of a particular subject that is superior to that generally acquired by ordinary individuals. 16 CFR 255.0(e). An expert endorser’s qualification must, in fact, give him or her the expertise that he or she is represented as possessing with respect to the endorsement. 16 CFR 255.3(a). An expert endorsement must be supported by an actual exercise of expertise, and the expert’s evaluation of the product must have been at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented. 16 CFR 255.3(b).

¹⁶⁹ 16 CFR 255.5. When there is a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement (*i.e.*, the connection is not reasonably expected by the audience), such connection must be fully disclosed. 16 CFR 255.5.

¹⁷⁰ 16 CFR 255.4.

evaluated the product.¹⁷¹ The marketer could avoid deception by using clear and prominent qualifying language to alert consumers that it created the certifying program.

Proposed Example 2 involves a marketer who displays a seal of approval bestowed by a trade association in which the marketer is a member. In this case, the trade association evaluated the environmental attributes of the marketer's product. Because the seal of approval implies that a third-party evaluated and certified the product, consumers likely expect that the endorsing party is truly independent from the marketer. In this case, however, the certifier is not a truly independent entity because the marketer pays membership dues to the association. Under Section 5 of the FTC Act, as explained by the Endorsement Guides, marketers are required to disclose a "material connection," or a "connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement."¹⁷² Accordingly, this example makes clear that the marketer's failure to disclose its material connection with the endorsing association, *i.e.*, that it is a dues-paying member of the endorsing association, is deceptive.

Proposed Example 3 similarly illustrates a failure to disclose a material connection and shows how the name of a certifying organization can be misleading. In this example, the marketer is a member of an industry trade association, the American Institute of Degradable Materials, that evaluates the biodegradability of its members' products. The association's name may lead consumers to believe that the association is an independent certifying organization. Consumers likely place different weight on a certification from an industry association than from an independent, third-party. Because this

¹⁷¹ See 16 CFR 255.0 (defining "endorsement" as a message which "consumers are likely to believe reflects the opinion . . . of a party other than the sponsoring advertiser") (emphasis added); 16 CFR 255.5 (stating that when there is a connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement, such connection must be fully disclosed); *see also Trade Advertising Assocs., Inc.*, 65 F.T.C. 650 (1964) (finding a newspaper's statement about "awards" it won, which were, in fact, created by the publisher, deceptive because consumers were misled into believing that an objective third-party had evaluated the newspaper); *Revco D.S., Inc.*, 67 F.T.C. 1158 (1965) (finding an advertiser's creation and use of a "Consumer Protective Institute" seal on products was deceptive because the seal created the false impression that "an independent and disinterested organization . . . had approved these products").

¹⁷² 16 CFR 255.5.

advertisement does not disclose that the certifier is an industry trade association, the advertisement is likely to be deceptive. As shown in the example, the marketer could avoid this deception by disclosing that the American Institute of Degradable Materials is an industry trade association.

Unlike the examples above, proposed Example 4 addresses a situation in which a marketer touts its relationship with a third party that has neither evaluated nor endorsed the environmental attributes of its products. In this example, the marketer displays a seal to show that it is a member of the "U.S. EcoFriendly Building Association." The proposed example makes clear that, in this circumstance, displaying the organization's seal may cause consumers to mistakenly believe that the organization has evaluated and endorsed the product. In this example, the marketer could avoid deception by stating that the seal refers to the company's membership only and that the association did not evaluate the product's environmental attributes.

b. Certifications and Seals as General Environmental Benefit Claims

The current Green Guides state that unqualified certifications and seals of approval likely convey general environmental benefit claims. Specifically, Example 5 of the current general environmental benefit section states that a marketer using an unqualified seal of approval should be able to substantiate the broad claim that the product is environmentally superior to others.¹⁷³ If the marketer cannot, it should accompany the seal with "clear and prominent qualifying language limiting the environmental superiority representation to the particular product attribute or attributes for which they could be substantiated . . ."¹⁷⁴ No commenters challenged this approach. Therefore, the Commission continues to believe that consumers likely interpret unqualified seals and certifications similarly to general environmental benefit claims.¹⁷⁵

As discussed in Part V.A, above, the Commission's consumer perception study shows that broad, general environmental benefit claims suggest that a product has specific, unstated green attributes, such as recyclability

¹⁷³ 16 CFR 260.7(a).

¹⁷⁴ *Id.*

¹⁷⁵ The Commission's study did not test consumer interpretation of seals of approval or certifications. Given the wide diversity of seal and certification designs, it would have been difficult to draw general consumer perception conclusions from testing a particular seal design. No commenter submitted relevant consumer perception evidence.

and biodegradability, and that the product has no negative environmental impact. The study results also reinforce the Guides' advice that marketers may be able to avoid making deceptive general environmental claims by qualifying those claims.

The Commission proposes transferring a modified Example 5 into the new certification section¹⁷⁶ and moving the guidance from this example into this section. Specifically, the guidance cautions marketers that unqualified seals of approval and certifications likely constitute general environmental benefit claims and, because marketers are unlikely to be able to substantiate such claims, they should not use unqualified certifications or seals of approval. The guidance further states that marketers should qualify seals of approval or certifications to prevent deception. Qualifying language should be clear and prominent and should convey that the seal of approval or certification applies only to a specific and limited benefit.¹⁷⁷ The Commission will consider whether the qualifying language successfully limits the general environmental benefit claim on a case-by-case basis.

In contrast, proposed Example 6 illustrates how a marketer can properly use a third-party certification for a single-attribute claim, *e.g.*, "chlorine-free." In this example, the name of the certifier ("No Chlorine Products Association") conveys that the certification applies only to one environmental attribute, rather than to the overall environmental benefit of the product.

c. Third-Party Certifications as Substantiation

Third-party certification may constitute adequate substantiation. Therefore, the following describes the Commission's proposed guidance on the use of certifications to substantiate environmental claims, as well as the topics the Commission declines to address.

A marketer may rely on a third-party certification as all or part of its substantiation if the marketer ensures that the certification constitutes competent and reliable scientific evidence to support its claims. In other

¹⁷⁶ This example is now Example 5 in the proposed new Section 260.6. The example now states that the environmental seal is likely to convey that the product has far-reaching environmental benefits and may also convey that it causes no negative environmental impact.

¹⁷⁷ It is possible for this qualifying language to be part of the certification or seal itself. For example, the name of a seal may constitute all or part of the qualification. *See* proposed Examples 2 and 6.

words, a marketer relying on a certification as substantiation must ensure that the certification supports each of the marketer's claims with tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.¹⁷⁸ This evidence should be sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that each of the claims is true. It is the marketer's responsibility to ensure that the certification adequately substantiates its claims. The proposed Guides, therefore, remind marketers that simply possessing a third-party certification does not eliminate their obligation to ensure that they have substantiation for their claims, including all claims communicated by the certification.

The Commission does not propose incorporating four suggestions raised by commenters. First, the Commission does not propose requiring marketers to obtain a third-party certification to substantiate their claims. Rather, Section 5 of the FTC Act gives marketers the flexibility to substantiate their claims with any competent and reliable scientific evidence.¹⁷⁹ Because the Guides interpret Section 5 as applied to environmental claims, requiring a third-party certification to substantiate claims is beyond the Guides' purview.

Second, the Commission does not propose establishing a particular certification system. The Green Guides do not establish environmental performance standards or identify environmentally preferable industry practices. Instead, the Guides' purpose is to provide advice regarding consumer interpretation of environmental marketing claims so that marketers can avoid making false or misleading claims.

Third, the Commission declines to propose guidance on the development of third-party certification programs. Experts in the field are in the best position in a dynamic marketplace to determine how to establish certification programs to assess the environmental

attributes of products. There may be multiple ways to develop standards that would constitute adequate substantiation, *i.e.*, substantiation that constitutes competent and reliable scientific evidence. Accordingly, the Commission will continue to evaluate the adequacy of a third-party certification as substantiation on a case-by-case basis.

Finally, the proposed, revised Guides do not provide that certifiers make their standards or any other criteria used to support their certifications public. Although Section 5 requires that marketers possess substantiation for their claims prior to making them, it does not require that marketers make their substantiation publicly available.

C. Degradable Claims

1. The Current Guides

The Guides state that an unqualified degradable claim should be substantiated with competent and reliable scientific evidence that the entire product or package will completely break down and return to nature within a reasonably short period of time after customary disposal.¹⁸⁰ The Guides also provide that degradable claims should be qualified to avoid consumer deception about: (1) the product or package's ability to degrade in the environment where it is customarily disposed; and (2) the rate and extent of degradation. For example, the Guides discuss a trash bag labeled "degradable," without qualification. The marketer relies on tests showing that the bag will degrade in the presence of water and oxygen. Because trash bags are customarily incinerated or buried in landfills that inhibit degradation by minimizing moisture and oxygen, the marketer lacks substantiation that the bags will degrade in a reasonably short period of time. Thus, the claim is deceptive.¹⁸¹

The Commission has challenged degradability claims more than any other specific claim addressed by the Green Guides.¹⁸² These cases were not based on products' inability to degrade under any conditions, but rather on

their inability to degrade in the manner consumers expect.

2. Comments

Most commenters supported the Commission's degradable claims guidance.¹⁸³ For example, the Soap and Detergent Association supported the Guides' provision that "degradability claims should be qualified to the extent necessary to avoid consumer deception about the product's ability to degrade in the environment where, or in the manner in which, it is customarily disposed."¹⁸⁴

Although supporting the current guidance, commenters suggested four modifications. First, many stressed that typical solid waste disposal treatments inhibit degradation.¹⁸⁵ Procter & Gamble summed up these views, stating "[i]n the United States, solid waste is predominantly disposed of by incineration or in a landfill, where little or no degradation occurs."¹⁸⁶ Consequently, these commenters argued that unqualified biodegradable claims are inappropriate for items destined for landfills and incinerators.¹⁸⁷ Second, several commenters recommended that the Commission provide guidance on the "reasonably short" time period for complete decomposition. For example, the Biodegradable Products Institute ("BPI") urged that "[t]he FTC . . . cite a specific timeframe for the process."¹⁸⁸ Third, several commenters suggested that the Commission reference technical protocols that marketers could follow to adequately substantiate degradable claims. These commenters did not form

¹⁸³ See, e.g., Biodegradable Products Institute ("BPI"), Comment 533431-00087 at 2 (supporting guidance, but proposing changes); EPA-EPPP, Comment 533431-00038 at 7; EPA-SPN, Comment 536013-00062 at 12; P&G, Comment 533431-00070 at 2.

¹⁸⁴ SDA, Comment 533431-00020 at 3; see also ACC, Comment 533431-00023 at 12.

¹⁸⁵ See CSPA, Comment 533431-00049 at 3 ("Very little, if any, degradation occurs when the product is incinerated or disposed of in a landfill."); Georgia-Pacific, Comment 533431-00007 at 9 ("[M]odern landfills are in fact entombment facilities where air, light and water are excluded by strict design. In those conditions, degradability time far exceeds 'the reasonable [sic] short period of time' of the Guides."); Tracy Artley, Comment 534743-00019 at 1; EHS, Comment 534743-00011 at 1; EPI, Comment 533431-00063 at 5; NAD, Comment 534743-00029 at 7; Tandus, Comment 533431-00021 at 1.

¹⁸⁶ P&G, Comment 533431-00070 at 2.

¹⁸⁷ No commenters specifically addressed disposal of liquid waste into wastewater treatment systems or aquatic environments.

¹⁸⁸ BPI, Comment 533431-00087 at 3; see also GPI, Comment 534743-00026 at 7 ("[I]t is important that the Commission provide additional clarification regarding what constitutes a 'reasonably short period of time.'"); Graphic Arts Coalition, Comment 533431-00060 at 1 ("The business community is now asking for a clearer definition of 'short period of time.'").

¹⁷⁸ 16 CFR 260.5.

¹⁷⁹ See Substantiation Policy Statement, 104 FTC at 840 (explaining that what constitutes a reasonable basis for claims depends on a number of factors); see also FTC, Dietary Supplements: An Advertising Guide for Industry (2001), available at (<http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf>) (stating that "[t]he FTC will consider all forms of competent and reliable scientific research when evaluating substantiation").

¹⁸⁰ 16 CFR 260.7(b).

¹⁸¹ *Id.*, Example 1. The FTC Staff's Business Brochure provides additional guidance, noting that a "reasonably short period of time" depends on where the product is disposed. The brochure explains that in landfills, where most trash is taken, materials degrade very slowly and certain materials take decades to decompose. FTC Staff's Business Brochure at 7.

¹⁸² See, e.g., *Dyna-E Int'l, Inc., et al.*, FTC Docket No. D-9336 (Dec. 15, 2009) (viscose towels); *Kmart Corp.*, FTC Docket No. C-4263 (July 15, 2009) (paper plates); *Tender Corp.*, FTC Docket No. C-4261 (July 13, 2009) (moist wipes and plastic packaging).

a consensus, however, regarding which specific protocol(s) the Commission should consider.¹⁸⁹ Finally, the EPA's Sustainable Products Network urged that the revised Guides address emerging "oxo-degradable" claims.¹⁹⁰

3. Consumer Perception Evidence

The Commission solicited from commenters evidence of consumer understanding of degradable claims. Only BPI referenced detailed research findings, which arose from a September 2006 survey conducted by the opinion research firm APCO Insight for the American Chemistry Council ("APCO survey").

FTC staff has subsequently reviewed the underlying questionnaire and data from the APCO survey.¹⁹¹ Using a widely-accepted methodology, the survey asked 1,000 Americans about unqualified biodegradable and compostable claims.¹⁹² It found that 60 percent of consumers believed that a biodegradable package will disappear in one year or less.¹⁹³ Additionally, 83 percent of consumers believed a biodegradable item will decompose even when disposed in a landfill.¹⁹⁴ The Commission is unaware of additional consumer perception data on degradable claims.¹⁹⁵

4. Analysis and Guidance

In light of the comments and the APCO survey, as well as our own enforcement experience, the Commission proposes retaining its

guidance on degradable claims but adding clarity regarding degradable claims for solid waste.¹⁹⁶ Given the lack of information on the record about liquid waste, the Commission seeks comment on whether it should provide additional specificity concerning claims for such materials. The Commission declines to advise marketers that a particular test constitutes adequate substantiation for degradability claims. Finally, the Commission proposes addressing oxo-degradable claims in the Guides.

a. Solid Waste – Time Period for Degradation

The Commission proposes revising the Guides to clarify that unqualified degradable claims are deceptive for products or packages destined for landfills, incinerators, or recycling facilities. Federal environmental regulations require landfills to minimize interaction with water, oxygen, and light.¹⁹⁷ Absent a robust supply of these elements, decomposition is severely retarded.¹⁹⁸ Moreover, incinerators combust materials at extreme temperatures, thereby completely preventing decomposition.¹⁹⁹ Together, landfills and incinerators received 66 percent of municipal solid waste in 2008.²⁰⁰ In addition, in 2008, another 24 percent of consumers' trash went to recycling facilities to be processed for reuse.²⁰¹ Thus, these materials also will not decompose. Accordingly, unqualified degradable claims for a vast majority of disposable solid items are likely to be deceptive because the customary methods of disposal do not present conditions for decomposition in a reasonably short period of time.

For those solid waste products that are not disposed of in these traditional ways, some marketers seek more definite guidance regarding what constitutes a "reasonably short period of time." The Commission, therefore, proposes the following two modifications to the Guides.

First, because the Guides do not currently illustrate a non-deceptive

unqualified degradable claim for a solid item, the Commission proposes adding an example. Specifically, proposed new Example 5 describes a plant pot that, when buried in soil, quickly decomposes. This example illustrates that an unqualified degradable claim can be made non-deceptively about a solid item if the item is customarily disposed of in a manner that promotes total and rapid decomposition.

Second, the APCO survey found that 60 percent of consumers expect biodegradable solid waste to decompose in one year or less. Accordingly, the Commission proposes adopting a maximum period of one year for complete decomposition of solid materials marketed as degradable without time qualification. The Commission requests comment on whether this one-year period may lead to deceptive claims where consumers would expect a material to degrade in a much shorter time frame – e.g., a plant pot decomposing fully in a single growing season.

b. Solid Waste – Substantiation

As discussed above, several commenters suggested that the Commission reference technical standards that marketers could follow to substantiate degradability claims.²⁰² Any technical protocol (or combination of protocols) must assure complete decomposition within one year and must replicate the physical conditions found in the relevant disposal environment (e.g., in landfills, where most trash is disposed). Commission staff has not identified testing protocols that satisfy these needs.²⁰³ Accordingly, the Commission does not propose creating a safe harbor for any particular technical standard.

c. Liquid Waste

The Commission received no comments concerning decomposition of liquids (or dissolvable solids) in wastewater or aquatic environments, and is unaware of consumer perception evidence relating to such degradable claims. Therefore, the Commission lacks sufficient information to give more

¹⁸⁹ The following commenters favor some degree of reference to technical standards or testing protocols: ECM BioFilms, Comment 534743-00011 at 3 (ASTM D 5526 (plastics under accelerated landfill conditions)); EPA-SPN, Comment 536013-00062 at 12 (various harmonized tests accessible online from the EPA); EPI, Comment 533431-00063 at 4 ("the applicable [unspecified] ASTM or ISO standard"); Georgia-Pacific, Comment 533431-0007 at 9-10 (the British Standards Institution's EN 14327:2000 (requirements for packaging and packaging waste) and ISO 14855:1999 (aerobic biodegradability of plastics)); SPI, Comment 533431-00036 at 8 ("existing [unspecified] ASTM standards"); see also Graphic Arts Coalition, Comment 533431-00060 at 1 ("The business community . . . oftentimes seeks a specific test method to verify the claims. Inclusion in the guides of acceptable test methods might be an appropriate step."); Tandus, Comment 533431-00021 at 1 ("If a test method could be specified, it might help qualification of such claims.")

¹⁹⁰ EPA-SPN, Comment 536013-00062 at 12 (discussing degradable, biodegradable, oxo-degradable, and photodegradable claims).

¹⁹¹ The Commission has placed this information on the public record.

¹⁹² The study did not explore other types of degradable claims, such as photodegradable.

¹⁹³ See APCO, Biodegradable and Compostable Survey Topline at 2.

¹⁹⁴ *Id.* at 1.

¹⁹⁵ The Commission's consumer perception study did not specifically ask consumers about unqualified biodegradable claims.

¹⁹⁶ This proposed guidance can be found in 16 CFR 260.8.

¹⁹⁷ See 40 CFR Part 258.

¹⁹⁸ EPA, *The Consumer's Handbook for Reducing Solid Waste*, EPA Pub. 530-K-96-003, at 17 (1996); William Rathje and Cullen Murphy, *Rubbish! The Archaeology of Garbage* 112 (2001).

¹⁹⁹ See National Research Council of the National Academy of Sciences, *Waste Incineration & Public Health* 37 (2000).

²⁰⁰ EPA, *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2008 at 2-3*, available at (<http://www.epa.gov/waste/nonhaz/municipal/pubs/msw2008rpt.pdf>).

²⁰¹ *Id.*

²⁰² The comments discussed numerous different standards. While no single protocol attracted wide support, the standards published by ASTM garnered the most mention.

²⁰³ Most trash is disposed in landfills, which have varied, highly compressed, heterogeneous zones. The moisture, temperature, and contact conditions in landfills differ from the laboratory protocols. ASTM D 5511, for example, mimics a rare disposal environment – a highly controlled anaerobic digester, such as may be found on farms or in sewage treatment systems – with consistent moisture, heat, and exposure to degradation catalysts.

definitive guidance on the “reasonably short period of time” for degradability claims for liquids.²⁰⁴ Accordingly, the Commission seeks consumer perception evidence regarding these degradable claims and requests comment on whether the Guides should specify a decomposition time period for liquid substances or dissolvable solids marketed without qualification.

d. Emerging Oxo-degradable Claims

The EPA’s Sustainable Products Network urged the Commission to include guidance concerning emerging degradable claims – “oxo-degradable” and “oxo-biodegradable.”²⁰⁵ Claims relating to purported oxo-degradability have entered the marketplace in connection with some of the same disposable items, e.g., bottles and bags, that have featured other degradable claims.²⁰⁶ According to relevant trade associations, the technology behind these claims depends upon a catalyst, typically light or oxygen, to commence and sustain the decomposition process.²⁰⁷ However, as discussed above, these elements are lacking in customary methods of disposal. Although commenters did not provide any consumer perception evidence relating to oxo-degradable claims, it is likely consumers would understand these claims similarly to other degradable claims.²⁰⁸ Therefore, the

²⁰⁴ Although one group of testing protocols for biodegradability in water emphasizes a 28-day period for “ready biodegradability,” these tests do not appear to ensure the complete decomposition of the substance. EPA Office of Prevention, Pesticides and Toxic Substances, 835.3110 Ready Biodegradability Guideline, Pub. EPA 712-C-98-076 (1998), available at (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/835_Fate_Transport_and_Transformation_Test_Guidelines/Series/835-3110.pdf).

²⁰⁵ EPA-SPN, Comment 536013-00062 at 6, 12.
²⁰⁶ See, e.g., *The recession: packaging fights back*, Packaging Today, Feb. 2009, at 32 (oxo-degradable bottle); *Print Media: Footprints with a lighter touch*, Marketing Week, Mar. 27, 2008, at 23 (oxo-biodegradable bag).

²⁰⁷ OxoBiodegradable Plastics Institute, Frequently Asked Question 11, (<http://www.oxobio.org/faq.htm#q4>) (“Heat and/or sunlight are required to initiate degradation and there has to be oxygen present.”); BPI, Background on Biodegradable Additives (Mar. 18, 2009) at 1 (“Oxo-biodegradables . . . theoretically foster oxidation and chain scission in plastics when exposed to heat, air and/or light.”).

²⁰⁸ The root word, degradable, is identical; consequently, consumers’ basic intuition about decomposition after customary disposal is likely to be the same, regardless of prefixes such as bio-, photo-, or oxo-. The National Advertising Division also found that oxo-biodegradable is similar to degradable. With respect to bags marketed as “100% oxo-biodegradable,” NAD recommended that the marketer discontinue the claim “and otherwise modify its advertising to avoid conveying the message that PolyGreen bags will quickly or completely biodegrade when disposed of through ‘ordinary channels,’ e.g., when placed in a landfill.”

Commission proposes treating oxo-degradable and oxo-biodegradable claims like all other degradable claims.²⁰⁹

D. Compostable Claims

1. The Current Guides

Currently, the Guides advise marketers to substantiate compostable claims with competent and reliable scientific evidence demonstrating that “all of the materials in the product or package will break down into, or otherwise become a part of, usable compost (e.g., soil-conditioning material, mulch) in a safe and timely manner in an appropriate composting program or facility, or in a home compost pile or device.”²¹⁰ Further, the Guides advise marketers to qualify compostable claims “to the extent necessary” to avoid consumer deception. For instance, they state: “A claim that a product is compostable in a municipal or institutional composting facility may need to be qualified” to alert consumers to any “limited availability of such composting facilities.”

The Guides provide six examples illustrating this guidance, including several relating to the limited availability of large-scale composting facilities. For instance, Example 4 discusses a product designed to be composted only in yard trimmings composting programs but merely labeled “compostable.” Such yard trimmings programs are not available to a substantial majority of consumers or communities where that particular product is sold. Consequently, the claim is deceptive, but could be corrected with a clear and prominent disclosure indicating the limited availability of such programs.

2. Comments

The comments on this issue were extremely limited. Some commenters suggested that the Guides state that two ASTM tests, specifications D 6400 and D 6868, constitute adequate substantiation for compostable claims.²¹¹

NAD Press Release Regarding GP Plastics Corp.’s PolyGreen Plastic Bags (Mar. 9, 2009).

²⁰⁹ For the purposes of interpreting and applying revised Section 260.8, the FTC considers the term “degradable” to include all variants, such as biodegradable, photodegradable, oxo-degradable, and oxo-biodegradable. Thus, degradable claims include any and all of the foregoing.

²¹⁰ 16 CFR 260.7(c).

²¹¹ BPI, Comment 533431-00087 at 4; EPA-EPFP, Comment 533431-00038 at 8; EPA-SPN, Comment 536013-00062 at 13; see also Earthcycle Packaging Ltd., Comment 534743-00005 at 1.

3. Consumer Perception Evidence

As discussed above, the Biodegradable Products Institute submitted a consumer research study conducted by APCO concerning degradable and compostable claims. According to this study, 62 percent of consumers said they do not have access, and an additional 28 percent do not know if they have access, to large-scale composting facilities.²¹² Nevertheless, 43 percent of consumers interpreted an unqualified compostable claim to mean that a large-scale composting facility is available in their area.²¹³ The study also found that 71 percent of consumers believed that a package labeled “compostable” would decompose in a home compost pile or device.²¹⁴

4. Analysis and Guidance

The Commission’s current compostable guidance is consistent with consumer perception data from the APCO survey. As discussed below, the Commission does not propose adding references to ASTM’s compostability tests to the Guides but proposes including advice concerning the “timely manner” of compost production.²¹⁵

a. Limited Availability of Composting Facilities

Large-scale composting facilities, particularly those taking feedstocks other than yard trimmings (e.g., leaves and grass), are still uncommon in the United States.²¹⁶ Unsurprisingly, 90 percent of consumers in the APCO survey reported having no access, or being unaware of access, to such facilities. Nevertheless, 43 percent interpreted an unqualified compostable claim to mean that such facilities are available in their area.

In light of the persistent scarcity of municipal facilities and many consumers’ mistaken belief about their availability, the Commission proposes retaining its advice that marketers qualify their compostable claims to avoid deception about the limited availability of composting facilities.²¹⁷

²¹² See APCO, Biodegradable and Compostable Survey Topline at 9.

²¹³ *Id.* at 8.

²¹⁴ *Id.* at 6.

²¹⁵ This proposed guidance can be found in 16 CFR 260.7.

²¹⁶ See *Food Composting Infrastructure*, BioCycle, Dec. 2008, at 30 (noting that in 2008, only 92 commercial composters and 39 municipal composters provided food waste composting); EPA, *Municipal Solid Waste in the United States: 2007 Facts and Figures* at 148, available at (<http://www.epa.gov/epawaste/nonhaz/municipal/pubs/msw07-rpt.pdf>) (“In 2007, there were 16 mixed waste composting facilities, two more than in 2006.”).

²¹⁷ Example 4 in the current Guides suggests an effective qualification that would convey the

Example 4 in the current Guides explains that this disclosure is needed when facilities “are not available to a substantial majority of consumers or communities.”²¹⁸ It does not, however, specify what proportion of consumers constitutes a substantial majority. As discussed below in the recyclable section, staff informally has interpreted “substantial majority” in the recycling context to mean at least 60 percent.²¹⁹

b. Substantiating Compostable Claims

Three commenters suggested that the Guides reference two laboratory protocols adopted by ASTM: (1) Standard specification D 6400 for compostable plastics; and (2) Standard specification D 6868 for biodegradable plastics used as coatings. The commenters, however, did not explain why these protocols would substantiate compostable claims and thereby meet consumers’ expectations about compostable products. Based upon a review of the protocols’ methodology, the Commission does not propose referencing these protocols in the Guides.

ASTM created D 6400 and D 6868 in response to manufacturers’ increased production of plant-based plastic resins.²²⁰ Marketers of these plant-based materials desired to contrast them with petroleum-based plastics and advertise them as “compostable.”²²¹ ASTM provides that a plastic item should be considered compostable if the item sufficiently converts to carbon dioxide under these protocols’ specific laboratory conditions.²²²

These protocols, however, have significant limitations. As a threshold matter, they apply to materials discarded only in scarce large-scale composting facilities, not home compost piles or devices.²²³ Moreover, the laboratory procedures ignore “wide variation” in actual composting facility operations, simulating instead “optimum conditions.”²²⁴

scarcity of large-scale facilities, e.g., “Appropriate facilities may not exist in your area.” 16 CFR 260.7(c), Example 4.

²¹⁸ *Id.*

²¹⁹ See Part V.E, *infra*.

²²⁰ See Rhodes Yepsen, *Compostable Products Go Mainstream*, BioCycle, July 2009, at 25.

²²¹ See *id.*; Susan Moran, *The New Bioplastics, More Than Just Forks*, N.Y. Times, Mar. 7, 2007.

²²² See ASTM D 6400 – 04 at § 4; ASTM D 6868 – 03 at § 4. These two protocols incorporate a third ASTM protocol, D 5338, a detailed test method for plastics disposed of in large-scale composting facilities.

²²³ See ASTM D 6400 at § 1.1; ASTM D 6868 at § 1.1.

²²⁴ See ASTM D 5338 – 98 (Reapproved 2003) at § 5.2 (“Because there is a wide variation in the construction and operation of composting systems and because regulatory requirements for

It is unclear whether these “optimum conditions” reflect real world conditions. There are no comprehensive, mandatory operating requirements for large-scale composting facilities.²²⁵ Instead, individual facilities appear to accept incoming plastic feedstock based upon a number of variables.²²⁶ Such variables include operator assumptions concerning whether the plastic is petroleum-based and the length of time an operator feasibly can wait to complete composting.²²⁷ Therefore, it is doubtful that there are typical large-scale composting practices consistent with the ASTM protocols, but more likely numerous and varied facility-specific restrictions on feedstock acceptance and processing.

Given this uncertainty, it does not appear that the ASTM protocols substantiate compostable claims. Therefore, the Commission does not propose referencing the ASTM standards in the Guides.

c. Time Period for Composting

As discussed above, the Commission proposes adding specificity to the degradable guidance in connection with the “period of time” for solid waste decomposition.²²⁸ Consistent with that advice, the Commission proposes to clarify the time period referenced in the

composting systems vary, this procedure is not intended to simulate the environment of any particular composting system. However, it is expected to resemble the environment of a composting process operated under optimum conditions.”). One example of such an optimum condition is the testing of only a small piece of the subject material – a two-centimeter scrap – rather than full-size plastic feedstock waste items.

²²⁵ EPA regulations contain detailed minimum requirements for landfills (40 CFR Part 258) and guidelines for incinerators (40 CFR Part 240). However, compost facility operations are not nationally standardized, apart from certain requirements applying to end-product safety – e.g., maximum hazardous materials levels (40 CFR Part 503). States and localities range widely in their governance of these facilities.

²²⁶ See, e.g., Lisa McKinnon, *Compostable Controversy*, Ventura County Star, Mar. 16, 2009 (noting that a facility cannot convert plastics to compost in a commercially viable way within 90 days); Press Release, Ohio University, Aug. 24, 2009, available at (<http://www.ohio.edu/outlook/08-09/August/791.cfm>) (stating that a modern facility cannot process a brand of plastic dining utensils in a timely manner); Janice Sitton, *Insider’s Guide to Compostables Collection at Events*, BioCycle, Aug. 2009, at 25 (“[P]roducts accepted for composting in one location may not be accepted for composting in another location. It all depends on the infrastructure and what a processor will accept as feedstock.”); Rhodes Yepsen, *Operation Insights: Compostable Products*, BioCycle, June 2008 (Facilities may reject certain plastics because visually they “are indistinguishable from conventional plastics” and can be “tricky to compost.”).

²²⁷ *Id.*

²²⁸ See Part V.C.4.a, *supra*.

compostable section (i.e., “timely manner”).²²⁹ Specifically, the Commission restates the position it articulated in its 1998 Green Guides review and proposes adding it to the compostable section.²³⁰ That is, “timely manner” means that the product or package will break down in approximately the same time as the materials with which it is composted, e.g., natural plant matter.

E. Recyclable Claims

1. The Current Guides

The current Guides provide that marketers should not advertise a product or package as “recyclable” unless “it can be collected, separated, or otherwise recovered from the solid waste stream for reuse, or in the manufacture or assembly of another package or product, through an established recycling program.”²³¹ The Guides further state that marketers should qualify recyclability claims to the extent necessary to avoid deceiving consumers about the limited availability of recycling programs and collection sites.

The Guides provide additional advice about the need for these disclosures and suggest qualifications depending on the level of available recycling facilities. Specifically, the Guides provide a three-tiered disclosure approach. First, when recycling facilities are available to a “substantial majority” of consumers or communities where the item is sold, marketers can make unqualified recyclable claims. Second, when facilities are available to a “significant percentage” of the population or communities, but not to a substantial majority, the Guides suggest that marketers qualify their claims by stating “This product [package] may not be recyclable in your area” or “Recycling programs for this product [package] may not exist in your area” or by providing the approximate percentage of communities or the population to whom programs are available.²³² Third, when recycling facilities are available to less than a significant percentage of communities or the population, the Guides recommend either disclosing that the product is recyclable only in the few communities with recycling facilities available for the particular product or stating the number of communities, the percentage of communities, or the percentage of the

²²⁹ GPI requested clarification on the “timely manner” guidance. Comment 534743-00026 at 8.

²³⁰ See 63 FR 24241 n.7 (May 1, 1998); FTC Staff’s Business Brochure at 7.

²³¹ 16 CFR 260.7(d).

²³² See *id.*, Examples 4, 6, and 7.

population where programs are available to recycle the product.²³³

The Guides further advise that the disclosure “recyclable where facilities exist” is not an adequate qualification where recycling facilities are not available to a substantial majority.²³⁴ Similarly, the FTC Staff’s Business Brochure cautions that the phrase “check to see if recycling facilities exist in your area” is an inadequate qualification where recycling is not available to a substantial majority.²³⁵

2. Comments

Recyclable claims garnered attention from many commenters. In particular, they addressed two issues: (1) the need for clarity regarding the “substantial majority” threshold; and (2) consumer confusion about the Society of the Plastics Industry code.

a. The Substantial Majority Threshold

As discussed above, the Guides advise marketers to qualify recyclable claims when recycling facilities are not available to a “substantial majority” of consumers or communities where a product is sold. Commenters identified difficulties in substantiating recyclable claims pursuant to this guidance. They did not agree, however, on how to modify the guidance, suggesting that the Commission either: (1) lower the substantial majority threshold; (2) quantify the substantial majority threshold; or (3) permit more positive disclosures when marketers do not meet the substantial majority threshold.

i. Lower the Substantial Majority Threshold

Several commenters urged the FTC to lower the Guides’ substantial majority threshold so that marketers could make an unqualified recyclable claim even when recycling facilities are not available to a substantial majority of consumers.²³⁶ Environmental Packaging International (“EPI”) suggested that the FTC consider a “middle ground,” where recyclability is available to “20 to 60 percent” of communities.²³⁷ According to EPI, in order to meet the substantial majority standard, marketers must send their packaging to numerous communities to determine whether they can be recycled. Thus, EPI opined that a more lenient threshold would reduce

this financial burden. An EPA staff member suggested that the substantial majority threshold may limit marketers’ ability to make recyclable claims for some products, which in turn may stifle efforts to develop recycling programs for those products.²³⁸

Other commenters suggested that the Commission consider adopting the ISO 14021 Environmental Labels and Declarations – Self-Declared Environmental Claims Standard.²³⁹ In contrast to the Guides’ “substantial majority” threshold, ISO 14021 provides that marketers can make unqualified recyclable claims if recycling facilities are available to a “reasonable proportion” of consumers where the product is sold.²⁴⁰ However, the ISO standard does not quantify its reasonable proportion threshold.²⁴¹

ii. Quantify the Substantial Majority Threshold

Several commenters indicated that complying with the recyclable guidance is difficult because the Guides do not quantify the substantial majority threshold. Although Commission staff has informally interpreted the substantial majority threshold to be “around 60 percent of consumers or communities,”²⁴² these commenters suggested that the Guides provide a specific percentage of consumers or communities that must have access to recycling to meet the threshold.²⁴³ For example, EPI opined that while there have been estimates of what constitutes a substantial majority, “these are not evident to businesses consulting the published Guides and should be made explicit in the document.”²⁴⁴

²³⁸ EPA, Green Packaging Workshop Tr. at 81, 92-93.

²³⁹ MeadWestvaco, Comment 533431-00013 at 2; Tetra Pak, Comment 536013-00012 at 2; Vinyl Institute, Comment 536013-00019 at 4-5.

²⁴⁰ ISO 14021 7.72:1999(E).

²⁴¹ Commenter MeadWestvaco explained that close alignment with global standards is critical to preventing market segmentation, yet because neither the Green Guides (with “substantial majority”) nor ISO (with “reasonable proportion”) has given numeric value to those terms, “confusion is commonplace.” Comment 533431-00013 at 2.

²⁴² See, e.g., Janice Frankle, Federal Trade Commission, Green Packaging Workshop Tr. at 100.

²⁴³ AF&PA, Comment 534743-00031 at 2 (stating that it “would be helpful for the FTC to clarify definition of ‘substantial majority’”); EPA, Green Packaging Workshop Tr. at 100 (recommending the FTC provide a “quantitative” interpretation of “substantial majority”); GreenBlue, Comment 533431-00058 at 3; Kate Krebs, National Recycling Coalition (“NRC”), Green Packaging Workshop Tr. at 92; see also International Paper, Comment 533431-00055 at 4 (noting that the access to recycling test needs to be made more explicit).

²⁴⁴ EPI, Comment 533431-00063 at 3; see also AF&PA, Comment 534743-00031 at 2 (clarifying the definition of “substantial majority” would encourage the recovery of more materials that have

iii. Permit Positive Disclosures for Recyclable Claims

Several commenters recommended that the Guides permit “positive” disclosures for recyclable claims where recycling facilities are not available to a substantial majority of consumers or communities.²⁴⁵ They contended that the Guides’ suggested disclosures (e.g., “this bottle may not be recyclable in your area”) do not provide any incentive for consumers to determine if the product may be recyclable. One commenter suggested that the Guides permit disclosures, such as “check to see if this product/package is recyclable.” According to that commenter, this disclosure would encourage consumers to inquire whether recycling facilities exist, perhaps by referring to websites.²⁴⁶

b. Use of the SPI Code

Developed by the Society of the Plastics Industry (“SPI”), the SPI code consists of a triangle composed of chasing arrows with a number in the middle that identifies the type of plastic resin from which a product is made. The Green Guides recognize that consumers may interpret the SPI code to mean that a package is recyclable because of its similarity to the universal recycling symbol, the three chasing arrows.²⁴⁷ To address this problem, the Guides explain that the SPI code is not likely to convey a recyclability claim if inconspicuously placed on the bottom of a product.²⁴⁸ In contrast, if the SPI code is displayed conspicuously, it is a “recyclable” claim necessitating disclosure of the limited availability of recycling programs for the product, if facilities are not available to a substantial majority of consumers.²⁴⁹

Several commenters observed that even inconspicuous use of the SPI code may cause consumer confusion.²⁵⁰ The Glass Packaging Institute, for example, asserted that consumers believe the SPI code indicates the packaging can be

the capacity to be recycled). Commenters also suggested that the FTC, or another agency, compile data concerning consumers’ access to recycling facilities for specific materials and provide a “safe harbor” list of materials that the FTC considers recyclable to a “substantial majority.” See, e.g., EPA, Green Packaging Workshop Tr. at 79-80; EPI, Comment 533431-00063 at 3; Estée Lauder, Green Packaging Workshop Tr. at 183; NRC, Green Packaging Workshop Tr. at 92.

²⁴⁵ See, e.g., Tetra Pak, Comment 536013-00012 at 2-3; Vinyl Institute, Comment 536013-00019 at 4-5.

²⁴⁶ Tetra Pak, Comment 536013-00012 at 2-3.

²⁴⁷ The three-chasing-arrows symbol is also known as the “Möbius Loop.”

²⁴⁸ 16 CFR 260.7(d), Example 2.

²⁴⁹ *Id.*

²⁵⁰ ABA, Comment 533431-00066 at 2-3; GPI, Comment 534743-00026 at 7.

²³³ See *id.*, Example 6.

²³⁴ See *id.*, Example 5.

²³⁵ FTC Staff’s Business Brochure at 8.

²³⁶ Sara Hartwell, EPA (“EPA”), Green Packaging Workshop Tr. at 81, 92-93; Tetra Pak, Comment 536013-00012 at 2; Vinyl Institute, Comment 536013-00019 at 4-5.

²³⁷ EPI, Green Packaging Workshop Tr. at 237-238.

recycled regardless of the consumer's geographic location.²⁵¹ Similarly, the American Beverage Association (“ABA”) observed that consumers interpret the SPI code – regardless of where the code is located, or what number is inside the code – to mean the package is “recyclable.”²⁵² The ABA argued that due to this incorrect belief, consumers discard non-recyclable packaging into recycling bins that then require extra sorting or ultimately result in contamination of the recycled plastic feedstock.²⁵³ These commenters urged the FTC to revise the Guides to clarify that the SPI codes are, in fact, recyclability claims that must be properly qualified.²⁵⁴

SPI countered that the Guides properly recognize that inconspicuous use of the SPI code is not a recyclability claim. It emphasized that the code was designed to help companies easily and quickly communicate the makeup of plastic packages to downstream consumers and recyclers sorting these products into various recycling streams.²⁵⁵ As such, SPI stated that it has guidelines, consistent with those mandated by state law, for the proper sizing and positioning of the code on containers and bottles.²⁵⁶ For example, SPI noted that its guidelines provide that the code “should be molded, formed or imprinted” and should appear on the bottom of the container, as close to the center as feasible, so that it can be quickly located and easily identified.²⁵⁷ SPI's guidelines also state that the code should “be applied where it will be inconspicuous to the consumer at the point of purchase so it does not influence the consumer's buying decision,” and “[r]ecyclable” and other environmental claims should not be made in close proximity to the code, even if such claims are properly qualified.²⁵⁸ According to SPI, if the FTC were to abandon its position that inconspicuous use of the SPI code is not an environmental claim, it would impose an undue burden on the plastics

industry and its customers who are complying with state law.²⁵⁹

3. Analysis and Guidance

The comments demonstrate the continuing importance of the recyclable section of the Guides. However, commenters suggested certain revisions to enhance the section's effectiveness for both businesses and consumers. The following analysis addresses these comments.²⁶⁰

a. The Substantial Majority Threshold

Commenters offered several recommendations regarding the substantial majority threshold for making unqualified recyclable claims, including lowering the threshold and quantifying the threshold. As explained below, the Commission does not believe that the record warrants lowering the threshold.²⁶¹ The Commission, however, requests comment on whether the Guides should formally quantify the threshold, and, if so, how.

i. Retaining the Substantial Majority Threshold

At the end of its 1998 Green Guides review, the Commission retained the substantial majority threshold, citing consumer perception research demonstrating that consumers are likely to perceive unqualified recyclable claims to mean that a product can be recycled in their community.²⁶² Several commenters in the current review disagreed with this decision and recommended that the Commission lower the threshold. No commenters, however, submitted consumer perception evidence that would warrant such a change.

Some commenters contended that the substantial majority threshold may stifle recycling efforts because it forces marketers to send their products or

packaging to numerous communities to determine if they can satisfy the threshold. Even if true, however, this argument would not provide a sufficient basis to revise the threshold. The purpose of the Green Guides is not to promote recycling or to minimize costs for marketers making recycling claims. Rather, it is to ensure that marketers' claims are consistent with consumer perception and thereby prevent deception. Commenters did not submit any evidence demonstrating that consumers have altered their view that an unqualified recyclable claim means that recycling facilities are available in their area. As a result, the Commission does not have any evidence that would warrant changing its conclusion.

As noted above, several commenters recommended that the Commission consider replacing the substantial majority threshold with the ISO 14021 “reasonable proportion” threshold. The ISO 14021 reasonable proportion standard arguably permits unqualified recyclable claims where less than a majority of communities have access to recycling facilities for a given product or package. However, because consumers interpret unqualified recyclable claims to mean that facilities are available in their area, the Commission has no basis for adopting this standard.

ii. Quantifying the Substantial Majority Threshold

As noted by several commenters, the ambiguity of the substantial majority standard causes problems. One marketer might interpret 55 percent as a substantial majority and, thus, make an unqualified recyclable claim. A competitor might believe that substantial majority means 75 percent and, thus, decline to make the same claim. Commission staff, therefore, has informally interpreted substantial majority to mean at least 60 percent.²⁶³

²⁶³ FTC Staff concluded that the 60 percent figure is an appropriate minimum threshold because it is consistent with the plain meaning of “substantial majority.” The adjective “substantial” requires that there be something greater than a simple majority. Sixty percent is not so high that it permits unqualified claims only when nearly all communities have recycling facilities. Staff further found that this figure is consistent with previous Commission statements and court decisions. *See, e.g.*, 73 FR 51164, 51177 (Aug. 29, 2008) (“[A] substantial majority of consumers dislike telemarketing calls that deliver prerecorded messages. . . . [A]t least 65 to 85 percent of consumers do not wish to receive prerecorded telemarketing calls.”); Report to Congress: Marketing Food to Children and Adolescents, at 3-4 (July 2008) (“In addition . . . , the companies accounted for 60% to 90% of U.S. sales. Therefore, the Commission believes that the companies that received and responded . . . were responsible for a substantial majority of expenditures for food and

²⁵¹ GPI, Comment 534743-00026 at 7; *see also* ISLR, Green Packaging Workshop Tr. at 141-42 (noting that consumers confusing the SPI code on corn-based polylactic (“PLA”) bottles with the three-chasing-arrows are inadvertently contaminating the recycling stream with bioplastics since most recycling facilities do not accept PLA).

²⁵² ABA, Comment 533431-00066 at 2.

²⁵³ *Id.* at 2-3.

²⁵⁴ *Id.* at 3; GPI, Comment 534743-00026 at 7.

²⁵⁵ SPI, Comment 533431-00036 at 6; SPI, Comment 534743-00034 at 1.

²⁵⁶ SPI, Comment 534743-00034 at 2.

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *Id.* at 3. According to SPI, 39 states have laws requiring use of the SPI code. SPI also commented that it is working to expand the resin identification code to address new types of plastics through an initiative with ASTM. SPI, Comment 533431-00036 at 7.

²⁶⁰ In addition to the changes discussed below, the Commission proposes revising footnote 4 in the recyclable section of the Guides. 16 CFR 260.7(d) n.4. The existing footnote states the Commission deems batteries labeled in accordance with the Mercury-Containing and Rechargeable Battery Management Act to be in compliance with the Guides. This footnote describes the required labeling in detail, but does not explain that manufacturers may apply to EPA to use alternative labels. Rather than explaining each provision of the Act in this footnote, the Commission proposes to simplify the note to simply state that batteries labeled in accordance with the Act are deemed in compliance with the Guides.

²⁶¹ This proposed guidance can be found in 16 CFR 260.11.

²⁶² 63 FR 24240, 24243 (May 1, 1998).

The Commission proposes to advise marketers of this informal guidance in a footnote in the Guides. The Commission also requests comment on whether the Guides should formally quantify “substantial majority,” and, if so, what the appropriate minimum figure should be.

The Commission also proposes to improve the readability of this section and to make clear in the text of the recyclable section that it is using a three-tiered analysis for qualifying recyclable claims. The appropriate qualifications vary depending upon whether recycling facilities are available to: (1) at least a substantial majority; (2) at least a significant percentage but not a substantial majority; or (3) less than a significant percentage of consumers or communities.²⁶⁴ Currently, the recyclable section provides this guidance only in the examples. By highlighting this guidance in the text, the information should be more accessible.

b. Use of Positive Disclosures

As noted above, several commenters recommended that the Guides permit positive disclosures where recycling facilities are not available to a substantial majority of communities or consumers (e.g., “check to see if facilities exist in your area”). The Commission previously determined that these types of positive disclosures, standing alone, are not sufficient to correct consumers’ misimpressions, and, in fact, may reinforce them. Prior to the 1998 revisions, the recyclable section expressly stated that “recyclable where facilities exist” was an appropriate disclosure. However, in 1998, the Commission highlighted consumer perception data suggesting that consumers interpreted this phrase and a similar phrase, “check to see if recycling facilities exist in your area,” to mean that recycling programs did, in fact, exist in their area.²⁶⁵ Based on that data, the Commission changed its

beverage marketing to children and adolescents during 2006.”); *Mihailovich v. Laatsch*, 359 F.3d 892, 909-10 (7th Cir. 2004) (75 percent is substantial majority); *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 39 (D.D.C. 2001) (59 percent is substantial majority).

²⁶⁴ The Commission does not propose quantifying a “significant percentage” at this time. The comments focused on the substantial majority threshold for making unqualified recyclable claims and did not discuss the significant percentage threshold for making certain qualified recyclable claims. It is unclear if providing guidance on this phrase would be useful for marketers. The Commission, therefore, requests comment on this issue.

²⁶⁵ 63 FR 24244 (May 1, 1998).

guidance and withdrew its approval of those disclosures.²⁶⁶

Commenters have provided no consumer perception evidence to alter this conclusion. The Commission, therefore, declines to include such disclosures in the Guides, and instead proposes to revise the Guides to make clear that, standing alone, “check to see” disclosures do not adequately qualify recyclable claims. The Commission proposes modifying existing Example 5 to illustrate that both disclosures – “recyclable where facilities exist” and “check to see if recycling facilities exist in your area” – are inadequate.

Although the Commission retains its finding that “check to see” disclosures standing alone are insufficient, such positive disclosures, including those referring to websites or toll-free telephone numbers, may be appropriate in combination with the disclosures that the Commission has provided in its examples. Thus, a disclosure such as “Recyclable – recycling programs for this product may not exist. Call 1-800-XXX-XXXX” likely would not be deceptive.

c. Use of the SPI Code

Although some commenters asserted that consumers perceive even inconspicuously placed SPI codes as recyclable claims, they did not provide any consumer perception evidence to support their assertions. In the absence of consumer perception evidence, the Commission does not propose modifying Example 2 of the recyclable guide, which discusses the use of the SPI code.

F. Recycled Content Claims

1. The Current Guides

The Guides provide that marketers may make a recycled content claim only for materials that have been recovered or otherwise diverted from the solid waste stream, either during the manufacturing process (pre-consumer) or after consumer use (post-consumer).²⁶⁷ To make a pre-consumer recycled content claim, an advertiser must substantiate that the pre-consumer material would otherwise have entered the solid waste stream.²⁶⁸ The Guides

²⁶⁶ *Id.* The Commission included an example in the Guides demonstrating that the “recyclable where facilities exist” disclosure is inadequate. 16 CFR 260.7(d), Example 5. The FTC Staff’s Business Brochure included an example specifying that the “check to see” disclosure was inadequate. FTC Staff’s Business Brochure at 8.

²⁶⁷ 16 CFR 260.7(e).

²⁶⁸ As illustrated by Example 1, spills and scraps that are normally reused by industry within the original manufacturing process – and that, therefore, would not normally have entered the waste stream – do not constitute recycled content.

do not advise marketers to distinguish between pre-consumer and post-consumer materials, but marketers may do so. Marketers must substantiate any express or implied claims about the specific amount of pre- or post-consumer content in their products.

The Guides further advise marketers that consumers interpret unqualified recycled content claims to mean that the entire product or package, excluding minor, incidental components, is made from recycled material. For products or packages that are only partially made of recycled material, marketers should qualify a recycled content claim to avoid consumer deception.²⁶⁹

Example 9 of the Guides indicates that a claim about the percentage of recycled content may be based on the annual weighted average of the recycled content in a product.²⁷⁰ The FTC Staff’s Business Brochure, however, cautions marketers not to use such averaging if reasonable consumers interpret the recycled content claim to mean that each labeled item contains at least the described amount of recycled content.²⁷¹

2. Comments

The commenters addressing recycled content claims discussed three main issues: (1) pre-consumer recycled content claims for textile products; (2) the distinction between pre- and post-consumer recycled content claims; and (3) the methods for calculating recycled content.

a. Pre-consumer Recycled Content Claims for Textiles

Several commenters stated that the Guides do not provide sufficient guidance regarding pre-consumer recycled content claims for textile products. For instance, the EPA’s Sustainable Products Network (“EPA-SPN”) stated that it would be helpful to have more specific guidance, including examples, to help determine whether certain materials qualify as pre-

²⁶⁹ The Guides also provide that marketers should qualify a recycled content claim for products containing used, reconditioned, or remanufactured components. A claim need not be qualified where it is clear that the recycled content comes from used, reconditioned, or remanufactured components. 16 CFR 260.7(e). None of the commenters addressed the Commission’s guidance on these issues.

²⁷⁰ *Id.*, Example 9: “A paper greeting card is labeled as containing 50% recycled fiber. The seller purchases paper stock from several sources and the amount of recycled fiber in the stock provided by each source varies. Because the 50% figure is based on the annual weighted average of recycled material purchased from the sources after accounting for fiber loss during the production process, the claim is permissible.”

²⁷¹ FTC Staff’s Business Brochure at 11.

consumer recycled content.²⁷² EPA-SPN noted that re-use of off-quality materials generated during the manufacturing process presents difficult questions and suggested that several factors may be relevant to determine whether such materials should be regarded as pre-consumer recycled content or as industrial scrap that is normally reused in the manufacturing process. EPA-SPN indicated that an important factor may be whether the material must undergo significant processing before it can be reused.²⁷³

Another commenter stated that the Guides do not account for innovation in the textile industry.²⁷⁴ It noted that, for years, the textile industry has sought to prevent material from entering the solid waste stream and that “down cycling” (such as using waste yarn as fiber fill in toys) was common. The commenter said that more recent innovations seek to create high value raw materials from the waste product and provided examples of such developments. This commenter sought guidance on whether such material could be considered recycled content.²⁷⁵

b. Distinction Between Pre- and Post-consumer Recycled Content

The commenters raised two issues with respect to the Guides’ distinction between pre-consumer and post-consumer recycled content. First, two commenters stated that the Guides should “eliminate the artificial distinction” between pre-consumer and post-consumer materials for recycled paper.²⁷⁶ Although it is not entirely clear, it appears that these commenters believe the Guides should advise marketers not to distinguish between the amount of pre-consumer and post-consumer materials used in an item. Rather, marketers should make claims only about the total amount of recycled content (which combines both pre- and post-consumer material).²⁷⁷

²⁷² EPA-SPN, Comment 536013-00062 at 2.

²⁷³ *Id.* at 2-3.

²⁷⁴ Valdese Weavers, Comment 536013-0006 at 1.

²⁷⁵ Another commenter recommended that the Guides allow pre-consumer recycled content claims if synthetic polymers change in form, such as from a chip to fiber to yarn. Designtex, Comment 533431-00024 at 1.

²⁷⁶ AF&PA, Comment 533431-00083 at 1-2; FBA, Comment 533431-00015 at 2. They contend that the overwhelming majority of fibers recovered and recycled are post-consumer, and that the distinction between pre-consumer and post-consumer materials “is not meaningful to the consumer.” *Id.*

²⁷⁷ Another commenter, however, recommended that the Guides continue to permit marketers to distinguish between pre-consumer and post-consumer materials. Amy Wilson, Comment 534743-00004 at 1. A different commenter recommended that the Guides should permit recycled content claims only for post-consumer

Second, another commenter recommended that the Guides adopt the ISO 14021 approach to post-consumer material.²⁷⁸ This commenter explained that ISO 14021 contains a more expansive definition of “post-consumer” material than the Guides because it includes “returns of material from the distribution chain.” The commenter argued that U.S. companies may be at a disadvantage relative to international companies that can claim a higher percentage of post-consumer recycled content under ISO 14021.²⁷⁹ The commenter urged the FTC to adopt ISO’s definition, noting that federal law requires government agencies to use such voluntary standards when they are available.²⁸⁰

c. Calculating Recycled Content

The commenters had differing opinions regarding the appropriate methods to calculate recycled content. Several recommended that the Guides continue to use the annual weighted average.²⁸¹ Others recommended revising the Green Guides to permit alternative calculation methods.²⁸² For example, one commenter recommended that the Guides permit the use of the annual weighted average for the specific company’s business or the use of an industry sector annual weighted average.²⁸³ Another argued that requiring each product to have a minimum percentage of recycled content may limit the ability of vertically-integrated manufacturers to use recycled content.²⁸⁴ Yet another

materials. Tracy Artley, Comment 534743-00019 at 1.

²⁷⁸ PRC, Comment 533431-00035 at 1-2, Comment 534743-00024 at 1-2, Comment 534743-00023 at 3. ISO 14021 defines post-consumer material as “[m]aterial generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product which can no longer be used for its intended purpose. This includes returns of material from the distribution chain.” ISO 14021 7.8.1.1(a)(2):1999(E).

²⁷⁹ PRC, Comment 534743-00024 at 2.

²⁸⁰ *Id.*

²⁸¹ Bailey, Comment 533431-00028 at 6; GreenBlue, Comment 533431-00058 at 8; NAIMA, Comment 533431-00042 at 15; SDA, Comment 533431-00020 at 3; Saint-Gobain, Comment 533431-00037 at 15; Stepan Company, Comment 533431-00011 at 3.

²⁸² AF&PA, Comment 533431-00083 at 2-3; Georgia-Pacific, Comment 533431-00007 at 9; MBDC, Comment 533431-00022 at 1-3; MeadWestvaco, Comment 533431-00013 at 2; Weyerhaeuser, Comment 533431-00084 at 6.

²⁸³ Georgia-Pacific, Comment 533431-00007 at 9.

²⁸⁴ MBDC, Comment 533431-00022 at 1-2. This commenter claimed that vertically-integrated manufacturers have difficulty achieving high per-product percentages because of challenges tracking materials in large operations, incorporating high percentages of recycled content in high-volume product lines, and using high percentages of recycled content in products without affecting their performance.

argued that the Commission should consider a “mass allocation” methodology that would permit recycled content “offsets.” Under this approach, a company could earn credits for using recycled content and allocate those credits to make claims for other products.²⁸⁵ Some commenters, however, argued that these alternative approaches could mislead consumers by implying that individual products have a greater percentage of recycled content than they actually do.²⁸⁶

3. Consumer Perception Evidence

The Commission’s consumer perception study tested respondents’ understanding of the phrase “made with recycled materials” as this claim appeared on three different products – wrapping paper, a laundry basket, and kitchen flooring. The study asked respondents whether a statement that a product is “made with recycled materials” suggests that all, most, or some of the materials were made with recycled material. The largest group, 35 percent, indicated that they would interpret the claim as meaning that “all” of the product was made with recycled materials, while 20 percent believed that “most” of the product was made with recycled materials.²⁸⁷

The study further explored which claims were implied by a product advertised as “made with recycled materials.” The responses to a closed-ended question indicated that 52 percent of respondents believe that a “made with recycled materials” claim suggests that the advertised product was recyclable.²⁸⁸ The study also used an open-ended question to explore this same point. In response, only three percent said that the statement suggests the product is recyclable. Not surprisingly, a majority, 57 percent, stated that the advertised product was made of recycled content.

²⁸⁵ Shaw Industries Group, Inc. (“Shaw”), Comment 533431-00050 at 1-3; *see also* Sappi, Comment 534743-00023 at 3-5 (recommending “credit system” for recycled content).

²⁸⁶ Bailey, Comment 533431-00028 at 6; Stepan Company, Comment 533431-00011 at 3.

²⁸⁷ Further, 26 percent stated that the claim means that “some” of the product was made with recycled materials; 15 percent stated that the claim does not suggest anything about how much of the product was made with recycled materials; and 5 percent stated they were not sure. These figures total 101 percent because of rounding. These percentages were derived by combining the responses to all claims that included the phrase “made with recycled materials” (*i.e.*, “made with recycled materials,” “green - made with recycled materials,” “eco-friendly - made with recycled materials,” and “sustainable - made with recycled materials”).

²⁸⁸ This number is net of the non-environmental control claim.

4. Analysis and Guidance

The comments sought additional guidance concerning recycled content claims, focusing mainly on pre-consumer recycled content claims for textiles, the distinction between pre- and post-consumer recycled content, and the appropriate methods for calculating recycled content. The Commission analyzes these issues as well as issues raised by its consumer perception study below.

a. Pre-consumer Recycled Content Claims for Textiles

Although the Guides do not specifically address textiles, they provide advice concerning recycled content claims for all products, including textiles. To constitute pre-consumer recycled content, materials must have been “recovered or otherwise diverted from the solid waste stream . . . during the manufacturing process (pre-consumer). . . .”²⁸⁹ Examples 1-3 in the current Guides discuss factors relevant to determining whether the material was diverted from the solid waste stream – the amount of reprocessing needed before reuse and whether the material is normally reused in “the original manufacturing process.” Specifically, when spilled raw materials and scraps undergo only “a minimal amount of reprocessing” and are “normally reused in the original manufacturing process,” they are not diverted from the solid waste stream (and, therefore, do not qualify as recycled content).²⁹⁰

The commenters’ discussion of innovations in the textile industry highlights difficulties in using the existing guidance to determine whether a particular material qualifies as recycled content.²⁹¹ The commenters explain that the textile industry for many years has sought to reuse waste materials from the manufacturing process and that recent innovations have allowed manufacturers to put that material to higher use. These innovative

²⁸⁹ 16 CFR 260.7(e). The Guides further specify that the advertiser must have substantiation that the material would otherwise have entered the solid waste stream.

²⁹⁰ See 16 CFR 260.7(e), Example 1; see also 16 CFR 260.7(e), Examples 2 and 3.

²⁹¹ The difficulty in determining whether material qualifies as pre-consumer recycled content is not exclusive to the textile industry. One commenter from the lumber industry expressed concern about the pre-consumer recycled content claims of its competitors. Weyerhaeuser, Comment 533431-00084 at 6. It asserted that some companies interpret recycled content to include chips produced by sawmills as a byproduct of lumber production. Weyerhaeuser stated that it did not believe that this was a common interpretation of recycled content and did not treat such materials as recycled content. *Id.*

processes likely do not divert the waste material from the solid waste stream because the material already was being reused (albeit in a lower value form). Despite the fact that these higher-use processes do not satisfy the Commission’s guidance on recycled content (diversion from the solid waste stream), they satisfy the two factors the Commission considers in determining if waste is diverted from the solid waste stream. Specifically, the innovations may involve significant reprocessing before the material can be reused, and the material may be reused in something different from the original manufacturing process. These innovations, therefore, reveal some ambiguity in the Commission’s current guidance.

The comments, however, did not address the broader issue of whether the Commission should revise its guidance for pre-consumer recycled materials generally, and, if so, what changes it should make.²⁹² For instance, the comments did not address whether the Commission should eliminate the factors it currently uses to determine if material is diverted from the solid waste stream. In addition, it is unclear whether consumers interpret recycled content to mean more than diversion from the solid waste stream. For example, do they believe that any material that is significantly reprocessed and reused constitutes recycled content? If material is reused in place of virgin material, do consumers consider that material recycled content? If, over time, it becomes standard practice within an industry to reuse certain material, do consumers still regard that material as constituting recycled content? The Commission, therefore, declines to propose changes to its guidance at this time.²⁹³ Instead, the Commission solicits comment on what changes, if any, it should make to its existing guidance on pre-consumer recycled content claims for all products. In particular, the Commission seeks evidence of consumer perception of pre-consumer recycled content claims.

b. Distinction Between Pre- and Post-consumer Recycled Content

Some commenters recommended that the Guides advise marketers to make claims only for the total amount of recycled content in an item, and not to

²⁹² One textile industry member suggested that recycled content claims hinge on whether there has been a change in form (e.g., from chip to fiber to yarn). In the Commission’s judgment, it is unlikely that consumers would perceive material as recycled content merely because of a change in form.

²⁹³ This guidance can now be found in 16 CFR 260.12.

distinguish between the amount of pre-consumer and post-consumer materials used in that item. The Commission does not propose adding this advice to the Guides. Currently, marketers making recycled content claims have the option to disclose whether the recycled content is pre-consumer or post-consumer. The Commission has no evidence that specific claims about the type of recycled content mislead consumers. In the absence of evidence that these terms are deceptive, the Commission declines to advise marketers that they should discontinue using them.

The Commission also does not propose incorporating the ISO 14021 definition of “post-consumer” material into the Guides. As discussed above, material returned from the distribution chain (e.g., overstock magazines) qualifies as “post-consumer” recycled material under ISO 14021. It is unlikely, however, that consumers would interpret such material as “post-consumer” recycled content because the material never actually reaches consumers. The commenters did not provide any consumer perception evidence to the contrary. Under the Guides, therefore, marketers may claim that this material constitutes recycled content, but not “post-consumer” recycled content.

c. Calculating Recycled Content

Currently, the Guides advise marketers that recycled content claims may be based on the annual weighted average of recycled content in an item.²⁹⁴ Certain commenters suggested that the Guides allow for alternative calculation methods, such as the average amount of recycled content within a product line or across all product lines, or an offset-based approach.²⁹⁵

The Commission does not propose making the suggested changes. As some commenters cautioned, claims based on these alternative calculation methods could mislead consumers by implying that products contain more recycled content than they actually do. Indeed, these approaches could permit marketers to make recycled content claims for products that do not contain any such material. For example, a marketer may sell residential carpeting

²⁹⁴ 16 CFR 260.7(e), Example 9.

²⁹⁵ As noted above, one commenter argued that requiring products to have a minimum percentage of recycled content may constrain the ability of vertically-integrated manufacturers to use recycled content. The Guides do not specify minimum recycled content levels for products. The Guides permit marketers to make recycled content claims for products with only a small percentage of recycled content, as long as the claims are adequately qualified.

that contains no recycled content and commercial carpeting that contains 50 percent. If the marketer believes that individuals are more interested than businesses in recycled content, it could choose to average the amount of recycled content in both products and then make a 25 percent recycled content claim for its residential carpeting (even though this carpeting contains no recycled content).²⁹⁶ Such a claim appears to be deceptive; therefore, without consumer perception evidence to the contrary, the Commission declines to sanction it.

The Commission, however, proposes retaining Example 9, which illustrates that using annual weighted average is not deceptive.²⁹⁷ The Guides have included this example since 1992, and there is no evidence that consumers have been deceived by recycled content claims based on this type of calculation. Moreover, it does not appear that consumers would likely be deceived by a percentage recycled content claim for a single product because their chances of getting a product with a lower percentage of recycled content is roughly the same as their chances of getting one with a higher percentage. At least theoretically, however, using annual weighted average could lead to deception. For example, a company could use two manufacturing sites to make the same product – one using recycled content but selling to local consumers who give little weight to this fact, and another using no recycled content but selling to local consumers who place a premium on products containing recycled materials. In this circumstance, the company could use the annual weighted average to make recycled content claims to the second set of consumers, even though those consumers would never receive products with such content. The Commission, therefore, requests comment on whether recycled content claims based on annual weighted average are misleading, and, if so, whether these claims should be qualified.

d. Unqualified Recycled Content Claims

The Guides currently advise marketers to qualify recycled content claims unless the entire product or package, excluding minor, incidental components, is made with recycled content. Any needed qualifications should specify the percentage of recycled content in the item. The Commission's study indicates that this

guidance remains valid. Specifically, a significant minority of respondents (35 percent) indicated that an unqualified recycled content claim means that all of the product was made with recycled materials. The Commission, therefore, proposes retaining this guidance.

e. Implied Claims

The results of the Commission's consumer perception study suggest that some consumers understand a "made with recycled materials" claim to convey a recyclable claim. In response to a closed-ended question, 52 percent of respondents indicated that they believed that a "made with recycled materials" claim suggested that the product was recyclable. In response to an open-ended question, however, only three percent of respondents stated that they thought the advertised product was recyclable.

Although the responses to the closed-ended questions suggest that many consumers may perceive an implied recyclable claim, the Commission does not propose advising marketers that make unqualified recycled content claims to disclose if their product is not recyclable. Even if some consumers do perceive an implied recyclable claim, their understanding appears to be accurate. The Commission's study asked respondents only about an unqualified "made with recycled materials" claim. Assuming marketers are following the Guides, they make unqualified recycled content claims only where the products are made from 100 percent recycled materials. Products that are made of 100 percent recycled materials appear to be recyclable.²⁹⁸ Assuming this is the case, marketers would be able to substantiate any implied claim that their product is recyclable. Therefore, the Commission does not propose advising marketers that make unqualified recycled content claims to disclose that the product is not recyclable. The Commission requests comment on this advice and seeks any additional consumer perception evidence addressing this issue.

The Commission also does not propose such guidance for marketers making qualified recycled materials claims, such as "made with 50 percent recycled materials." It is unclear whether consumers believe that a qualified recycled materials claim suggests that the product is also recyclable. Without such evidence, the Commission is hesitant to advise

marketers to make such disclosures. The Commission, nevertheless, requests comment on its proposal and, in particular, seeks any consumer perception evidence.

G. Ozone-Safe and Ozone-Friendly Claims

1. The Current Guides

The current Guides state that it is deceptive to misrepresent, directly or by implication, that a product is safe for, or "friendly" to, the ozone layer or the atmosphere.²⁹⁹ This section contains four examples.

Example 1 provides that an ozone friendly claim is deceptive if the product "contains any ozone-depleting substance, including those listed as Class I or Class II chemicals in Title VI of the Clean Air Act Amendments of 1990, Pub. L. No. 101-549, and others subsequently designated by the EPA as ozone-depleting substances."³⁰⁰

Example 2 illustrates that an ozone friendly claim may be deceptive, even if the product does not contain ozone-depleting chemicals. In this example, an aerosol air freshener is labeled "ozone friendly" but contains volatile organic compounds, which may cause smog. Even though the product does not contain ozone-depleting substances, the unqualified ozone friendly claim is deceptive because it inaccurately conveys that the product is safe for the atmosphere as a whole.

Example 3 discusses an unqualified claim that an aerosol product "contains no CFCs." Although the product does not contain CFCs, it contains HCFC-22, another ozone-depleting substance. Because the no-CFCs claim likely implies that the product does not harm the ozone layer, the claim is deceptive.

Finally, Example 4 illustrates a qualified comparative ozone-related claim that is unlikely to be deceptive. This example states that a product is labeled "95% less damaging to the ozone layer than past formulations that contained CFCs," and explains that the manufacturer has substituted HCFCs for CFC-12. If the marketer can substantiate the decrease in ozone depletion, this qualified comparative claim is not likely to be deceptive.

2. Comments

Several commenters discussed the Guides' treatment of ozone-safe and no-CFCs claims. The EPA's Stratospheric

²⁹⁹ 16 CFR 260.7(h).

³⁰⁰ Example 1 also notes that Class I chemicals include chlorofluorocarbons (CFCs), halons, carbon tetrachloride, 1,1,1-trichloroethane, methyl bromide, and hydrobromofluorocarbons (HBFCs) and that Class II chemicals are hydrochlorofluorocarbons (HCFCs).

²⁹⁶ For mathematical simplicity, the hypothetical assumes equal sales of each product.

²⁹⁷ 16 CFR 260.7(e), Example 9.

²⁹⁸ Although relatively few products are made from 100 percent recycled materials, those that are – including some paper products and some glass products – appear to be recyclable. See, e.g., (<http://www.epa.gov/wastes/conservation/materials/paper/faqs.htm>).

Protection Division (“EPA-SPD”), which regulates ozone-depleting substances, stated that the Guides should continue to provide guidance concerning ozone-safe claims and allow marketers to use no-CFCs claims.³⁰¹ The EPA-SPD explained that no-CFCs claims may provide useful information to consumers because many consumers do not realize that CFCs are no longer used. Other commenters disagreed, and argued that the Guides should advise marketers not to make no-CFCs claims.³⁰² One commenter stated that because CFCs have been banned for almost 30 years, no-CFCs claims do not distinguish a marketer’s product from other CFC-free products.³⁰³ Another similarly stated that “given the universal ban on ozone depleting substances,” ozone-safe claims imply that products without that claim contain ozone-depleting substances. Therefore, the commenter argued that “there really is no reason to continue use of this claim.”³⁰⁴

In addition to the general discussion regarding ozone-safe and no-CFCs claims, the EPA-SPD recommended several modifications to the examples in the Guides.³⁰⁵ First, the EPA-SPD stated that the Commission should delete the references to HCFC-22 in Examples 3 and 4 because of EPA’s general prohibition on the use of newly produced ozone-depleting chemicals HCFC-22 and HCFC-14b. Second, the EPA-SPD recommended that the Commission provide guidance for air conditioning manufacturers that substitute non-ozone depleting refrigerants for the prohibited HCFCs. Specifically, EPA-SPD suggested advising marketers not to make unqualified “environmentally friendly” claims about their air-conditioning equipment. The EPA-SPD noted this equipment still may have adverse environmental effects because it uses large quantities of energy and because its refrigerants are greenhouse gases.³⁰⁶

³⁰¹ Letter from the EPA Stratospheric Protection Division, Mar. 18, 2010, available at (<http://www.ftc.gov/green>).

³⁰² Several commenters also mentioned no-CFCs claims, but only to provide context for their recommendation that the Commission provide guidance on free-of claims generally, which the Commission discusses in detail in Part V.H below. Eastman Chemical Company (“Eastman”), Comment 533431-00051 at 2; GPI, Comment 534743-00026 at 11; GreenBlue, Comment 533431-00058 at 4; SPI, Comment 533431-00036 at 10.

³⁰³ TerraChoice, Comment 533431-00040 at 1, attached report “The Six Sins of Greenwashing” at 4.

³⁰⁴ EHS, Comment 534743-00011 at 2.

³⁰⁵ Letter from the EPA Stratospheric Protection Division.

³⁰⁶ At least with respect to ozone-depletion claims for packaging, one commenter offered a

3. Analysis and Guidance

Based on the record, the Commission proposes retaining its guidance regarding ozone-safe claims.³⁰⁷ Below, the Commission addresses the two specific issues raised by commenters: (1) the use of no-CFCs claims; and (2) modification to the Guides’ examples.

First, the Commission does not propose advising marketers to avoid using no-CFCs claims. Although CFCs have been banned for years, the Commission agrees with EPA-SPD that many consumers may not realize this is the case. Consumers may still associate CFCs with certain products, such as aerosol sprays. No-CFCs claims may provide valuable information to these consumers who might otherwise assume that certain products have the negative environmental effects associated with CFCs. This conclusion is consistent with the Commission’s proposed guidance concerning no or free-of claims generally, discussed below.³⁰⁸ The Commission, however, seeks any consumer perception evidence concerning no-CFCs claims.

Second, the Commission proposes deleting current Examples 3 and 4 in the Guides, which both reference HCFC-22, in light of EPA’s general prohibition on its use. The Commission, however, proposes adding a new example, as recommended by the EPA-SPD, to illustrate that “environmentally friendly” claims by an air conditioning equipment manufacturer may be deceptive, even if the manufacturer has substituted non-ozone depleting refrigerants. This general environmental benefit claim likely would convey to consumers that the product has far reaching environmental benefits. Because currently available air conditioning equipment relies on refrigerants that are greenhouse gases and also consume a substantial amount of energy, this claim likely would be deceptive.

H. Free-of and Non-toxic Claims

1. The Current Guides

The current Guides do not contain a section that specifically addresses claims that products or services have no, are free of, or do not contain certain substances (“free-of claims”) or that they

different view, stating that ozone-related claims are no longer of significant relevance because of changes in packaging. GPI, Comment 534743-00026 at 11.

³⁰⁷ This proposed guidance can be found in 16 CFR 260.10.

³⁰⁸ Specifically, the Commission proposes that a claim that a product does not contain a substance may be deceptive if that substance has never been associated with the product. category.

are non-toxic. The current Guides, however, include three examples that address such claims.

Example 4 in the “overstatement of environmental attribute” portion of Section 260.6 discusses a “chlorine-free bleaching process” claim for coffee filters.³⁰⁹ The coffee filters are bleached without chlorine, but with a process that releases a reduced, but still significant, amount of the same harmful byproducts associated with chlorine bleaching. The claim, therefore, likely overstates the product’s benefits because consumers likely would interpret the claim to mean that the manufacturing process does not cause any of the environmental harm that chlorine bleaching does.³¹⁰

Example 4 in the general environmental benefit claims section addresses claims that a lawn care pesticide is “essentially non-toxic” and “practically non-toxic.”³¹¹ Consumers likely would interpret these claims to mean that the pesticide does not pose any risk to both human health and the environment. The example states that the claims would be deceptive if the pesticide poses a significant risk to either.

Finally, Example 3 in the ozone safe and ozone friendly section discusses an unqualified claim that an aerosol product “contains no CFCs.”³¹² Although the product does not contain CFCs, it contains another ozone depleting substance. Because the no-CFCs claim likely implies that the product does not harm the ozone layer, the claim is deceptive.

2. Comments

a. Free-of Claims

Numerous commenters recommended that the Commission provide further guidance regarding free-of claims. Several noted that the Guides address no-CFCs claims only in an example and suggested that the Commission address free-of claims generally.³¹³

Several commenters discussed the appropriate standard for determining whether a product is free of a

³⁰⁹ 16 CFR 260.6(c), Example 4.

³¹⁰ Example 4 provides a qualified claim – “bleached with a process that substantially reduces, but does not eliminate, harmful substances associated with chlorine bleaching” – that likely would not be deceptive.

³¹¹ 16 CFR 260.7(a), Example 4.

³¹² 16 CFR 260.7(h), Example 3.

³¹³ Eastman, Comment 533431-00051 at 2; GPI, Comment 534743-00026 at 11; GreenBlue, Comment 533431-00058 at 4; SPI, Comment 533431-00036 at 10. One commenter noted that because CFCs have been banned it is not clear whether the Guides’ treatment of no-CFCs claims would also apply to other substances. Eastman, Comment 533431-00051 at 2.

substance.³¹⁴ One argued that a product is not free of a substance if the substance is present at greater than background or regulated levels.³¹⁵ Similarly, one commenter noted that under the ISO 14021 standard, marketers can make free-of claims only if the “specified substance is no more than that which would be found as an acknowledged trace contaminant or background level.”³¹⁶ Finally, another contended that free-of claims should be substantiated by evidence that: “(1) none of the chemical was added during the manufacturing process, and (2) when tested, the product does not emit or off-gas levels of the chemical that are material to consumers, *i.e.*, in the context of health considerations, no more than background and applicable health-based standards for safe exposure.”³¹⁷

Several commenters stated that truthful free-of claims may be misleading. For example, some commenters raised concerns that a truthful free-of claim could mislead consumers if the marketer does not disclose that the product contains other substances that may be harmful to the environment.³¹⁸ Others stated that a claim that a product is free of a substance may be deceptive if the substance is not typically associated with the product and competitors’ products do not typically contain the substance.³¹⁹ One commenter noted that the ISO 14021 standard does not permit free-of claims if the substance has never been associated with the product.³²⁰ Another commenter illustrated this point with an “extreme hypothetical,” in which a marketer’s claim that its fruit juice does not contain cyanide could

mislead consumers by suggesting that other fruit juices do.³²¹

Several commenters raised two concerns that unqualified free-of claims imply other environmental claims.³²² First, they stated that while a free-of claim explicitly conveys that a product does not contain a certain substance, it also implies that a product is superior to other products that contain the substance.³²³ They argued that free-of claims should be qualified to inform consumers of the basis of the comparison, such as whether the free-of claim is relevant to the environmental or health risks or the performance of the product.³²⁴ Second, they asserted that free-of claims are often general claims of environmental benefit, *i.e.*, claims that products without the specified substance are good for the environment.³²⁵ They recommended that such claims not be permitted without qualifying language that substantiates both the express claim and all implied claims.³²⁶

Other commenters, however, stated that free-of claims may provide valuable information to consumers and do not necessarily imply additional comparative or general environmental benefit claims.³²⁷ One commenter explained that these claims should be qualified only if they are susceptible to more than one interpretation by a non-insignificant portion of the target audience and at least one such interpretation is false, misleading, or unsubstantiated.³²⁸ They recommended that the Commission not establish a bright-line rule requiring that marketers qualify all free-of claims.³²⁹

The National Advertising Review Council submitted comments summarizing the National Advertising Division (“NAD”) cases addressing environmental claims, including several cases that involved claims that products were free of, or did not contain, certain substances.³³⁰ In one case, the NAD found that a manufacturer adequately substantiated a formaldehyde-free claim for insulation.³³¹ The NAD concluded

that it was appropriate for the advertiser to make a formaldehyde-free claim, even if the insulation emitted a *de minimis* amount of formaldehyde because it would be inconsequential to consumers. The NAD noted that the determination of whether an amount is *de minimis* depends on the substance at issue and requires a case-by-case analysis.

b. Non-toxic Claims

Commenters discussed several issues raised by non-toxic claims.³³² One commenter stated that a non-toxic claim is vague, noting that everything is toxic in sufficient doses.³³³

The EPA’s Sustainable Products Network (“EPA-SPN”) stated that, consistent with the example in the current Green Guides, consumers likely would interpret non-toxic claims broadly. Accordingly, the EPA-SPN stated that non-toxic claims should be supported by evidence that addresses health and environmental effects for all exposed populations.³³⁴

The EPA-SPN also noted that non-toxic claims based on regulatory definitions may mislead consumers.³³⁵ The EPA-SPN stated that regulatory agencies typically set thresholds to identify moderate to high toxicity levels, and the fact that a substance does not exceed the regulatory standard does not necessarily mean that it is non-toxic.³³⁶

Addressing specific products, two commenters stated that insulation manufacturers make non-toxic claims but use toxic fire retardants.³³⁷ These commenters recommend prohibiting non-toxic claims if the product contains toxic substances in amounts of 10 percent of weight or more.

3. Analysis and Guidance

The Commission agrees with commenters that it should provide expanded guidance for free-of and non-toxic claims. Accordingly, the Commission proposes including a new Guides section to address these claims.³³⁸ The Commission also proposes moving two of the three

comparative claims that, without proper support, raised doubts about the safety of competing products. *Id.*

³³² EPA-SPN, Comment 536013-00062 at 4; Seventh Generation, Comment 533431-00033 at 6; TerraChoice, Comment 533431-00040, attached report “The Six Sins of Greenwashing” at 3.

³³³ TerraChoice, Comment 533431-00040, attached report “The Six Sins of Greenwashing” at 3.

³³⁴ EPA-SPN, Comment 536013-00062 at 4.

³³⁵ *Id.*

³³⁶ *Id.*

³³⁷ NAIMA, Comment 533431-00042 at 8; Saint-Gobain, Comment 533431-00037 at 9.

³³⁸ This proposed guidance can be found in 16 CFR 260.9.

³¹⁴ CSPA, Comment 533431-00049 at 4; EHS, Comment 533431-00057 at 1; Johns Manville, Comment 536013-00034 at 4. Several commenters stated that generic “chemical-free” claims are misleading because nothing is actually chemical-free. EHS, Comment 533431-00057 at 1; OMI, Comment 536013-00022 at 1; TerraChoice, Comment 533431-00040, attached report “The Six Sins of Greenwashing” at 3.

³¹⁵ EHS, Comment 533431-00057 at 1.

³¹⁶ CSPA, Comment 533431-00049 at 4 (quoting ISO 14021). Another commenter recommended that the Commission look to ISO 14021 for guidance on free-of claims. 3M Company, Comment 533431-00027 at 3.

³¹⁷ Johns Manville, Comment 536013-00034 at 2.

³¹⁸ See, e.g., GPI, Comment 534743-00026 at 11; NAIMA, Comment 533431-00042 at 10-11; Saint-Gobain, Comment 533431-00037 at 9-10.

³¹⁹ CSPA, Comment 533431-00049 at 4; Johns Manville, Comment 536013-00034 at 2; NAIMA, Comment 533431-00042 at 10; Saint-Gobain, Comment 533431-00037 at 9-10; TerraChoice, Comment 533431-00040, attached report “The Six Sins of Greenwashing” at 4.

³²⁰ CSPA, Comment 533431-00049 at 4.

³²¹ NAIMA, Comment 533431-00042 at 10.

³²² ACC, Comment 533431-00023 at 4; Formaldehyde Council, Comment 533431-00047 at 2-3; Vinyl Institute, Comment 533431-00046 at 2-3.

³²³ *Id.*

³²⁴ *Id.*

³²⁵ *Id.*

³²⁶ *Id.*

³²⁷ Eastman, Comment 533431-00051 at 2-3; Johns Manville, Comment 536013-00034 at 3-5.

³²⁸ Johns Manville, Comment 536013-00034 at 3.

³²⁹ Eastman, Comment 533431-00051 at 2; Johns Manville, Comment 536013-00048 at 3-4.

³³⁰ NAD, Comment 534743-00029 at 4.

³³¹ Although the NAD determined that the formaldehyde-free claim was appropriate, it also found that the manufacturer should discontinue

examples in the current Guides, cited above, into this section, and adding an additional example.

a. Free-of Claims

Marketers can always substantiate free-of claims by confirming that their products are, in fact, completely free of the relevant substance. As noted above, however, commenters raised a more difficult issue: whether marketers should be able to make free-of claims if their products contain background levels or trace amounts of a substance. No commenters provided evidence regarding how consumers interpret free-of claims. Accordingly, the Commission must apply its own expertise to determine how consumers likely would interpret such claims. Consistent with the NAD decision, discussed above, the Commission proposes advising that free-of claims may be appropriate where a product contains a *de minimis* amount of a substance that would be inconsequential to consumers. To illustrate this point, the Commission proposes adding a new example. In proposed Example 2, an insulation seller advertises its product as “formaldehyde-free.” Although the seller does not use formaldehyde as a binding agent to produce the insulation, tests show that the insulation emits trace amounts of formaldehyde. The seller has substantiation that formaldehyde is produced both synthetically and at low levels by people, animals, and plants; that the substance is present in most indoor and (to a lesser extent) outdoor environments; and that its insulation emits lower levels of formaldehyde than are typically present in outdoor environments. In this context, the trace amount of formaldehyde likely would be inconsequential to consumers, and, as a result, a formaldehyde-free claim likely would not be deceptive.

However, as the NAD cautioned, the determination of what constitutes *de minimis* depends upon the substance at issue and, therefore, requires a case-by-case analysis. In some cases, consumers may view the presence of even trace amounts of a substance as material. For example, trace amounts of a substance such as mercury, which is toxic and may accumulate in the tissues of humans and other organisms, likely would be relevant to consumers.³³⁹

As suggested by several commenters, the Commission proposes cautioning marketers that an otherwise truthful free-of claim may nevertheless be deceptive. For example, it may be

deceptive if a marketer claims that its product is free of a particular substance but does not disclose that the product contains another substance that may cause environmental harm, particularly if it is the same type of harm caused by the absent substance. To illustrate this point, the Commission proposes moving the chlorine-free coffee filter example, discussed above, into the new proposed section.

The Commission also proposes advising marketers that an otherwise truthful claim that a product is free of a substance may be deceptive if the substance has never been associated with that product category. This proposed guidance is consistent with ISO 14021’s free-of standards.³⁴⁰ Such claims may deceive consumers by falsely suggesting that competing products contain the substance or that the marketer has “improved” the product by removing the substance. However, in some circumstances, these claims may provide useful information to consumers who are interested in knowing whether a particular substance is present in a product. This could be the case, for example, where products in one category contain a substance and products in a competing category do not. Marketers making such “free-of” claims can minimize the risk of deception if they clarify that the entire product category is free of the substance. The Commission solicits comment on what guidance it should give for “free-of” claims based on substances which have never been associated with a product category. The Commission also seeks consumer perception evidence regarding these claims.

The Commission also agrees with several commenters that free-of claims may, depending on the context, convey that the product has broad environmental benefits or is environmentally superior to competing products. Thus, a marketer who makes a free-of claim that reasonable consumers would interpret to convey additional environmental claims must have substantiation for all of those claims.³⁴¹ The Commission, however, declines to advise that all free-of claims be qualified. In the absence of evidence

³⁴⁰ ISO 14021 states that free-of claims should not be based on “the absence of ingredients or features which have never been associated with the product category.” ISO 14021 5.7(p):1999(E). See also Environmental Claims: A Guide for Industry and Advertisers, Competition Bureau Canada, Canadian Standards Association, June 25, 2008, Clause 5.17.

³⁴¹ If reasonable consumers would interpret a particular free-of claim as making a general environmental claim, then the marketer should comply with the guidance in revised Section 260.4 regarding general environmental benefit claims.

that reasonable consumers would, no matter the context, perceive free-of claims as making implied general environmental benefit or comparative superiority claims, such guidance is not appropriate.

b. Non-toxic Claims

The Commission proposes moving its guidance concerning non-toxic claims from the existing example in current Section 260.7(a) to the proposed new Section 260.9.³⁴² This proposed section states that consumers likely think a non-toxic claim conveys that a product is non-toxic both for humans and for the environment. This section also advises marketers to qualify non-toxic claims to the extent necessary to avoid consumer deception.

Marketers should use caution when relying on regulatory standards as substantiation for claims that products are non-toxic. Reasonable consumers would likely interpret non-toxic claims to mean that a product is not harmful to humans or to the environment. Yet, as EPA-SPN noted, some regulatory thresholds allow moderately to highly toxic substances that do not meet these consumer expectations. Therefore, marketers should examine the scope and purpose of the regulatory standard to ensure that it substantiates a non-toxic claim in light of consumer expectations. For example, the standard for acute toxicity, which measures the effects of the substance from exposure during a short time period, may not provide an appropriate basis for non-toxic claims if the substance may be toxic to humans or the environment over a longer period of time.

I. Source Reduction Claims

Section 260.7(f) of the Guides states that it is deceptive to misrepresent that a product or package has been reduced in size or is lower in weight, volume, or toxicity. The Guides advise marketers to qualify source reduction claims to avoid deception about the amount of the reduction and the basis for any comparison. The Soap and Detergent Association agreed that marketers should qualify source reduction claims and “measure source reduction through a ‘package weight per unit or use of the product’ approach as well as physical reduction of packaging material.”³⁴³ No comments suggested modifying the guidance in this section. The Commission, therefore, proposes retaining this section without change.³⁴⁴

³⁴² The Commission also proposes moving the example into this new proposed section.

³⁴³ SDA, Comment 534743-00028 at 2.

³⁴⁴ This guidance can now be found in 16 CFR 260.16.

³³⁹ See 75 FR 41696, 41715 (July 10, 2010) (requiring that labels for compact fluorescent light bulbs disclose that the bulbs contain mercury).

J. Refillable Claims

Section 260.7(g) states that it is deceptive to misrepresent that a package is refillable. It advises marketers not to make an unqualified refillable claims unless: (1) they provide a system to collect and return the package for refill; or (2) consumers can refill the package with a separately purchased product. The Glass Packaging Institute stated that this guidance remains useful, and no other commenters recommended changes.³⁴⁵ The Commission, therefore, proposes retaining this section.³⁴⁶

VI. Claims Not Addressed by the Current Green Guides

The Commission asked commenters to discuss whether and how the Guides should be modified to address the use of environmental marketing claims that either are new or were not common during the last Guides review. Commenters discussed five types of claims: (1) sustainable; (2) organic/natural; (3) made with renewable materials; (4) made with renewable energy; and (5) carbon offsets. For each of these claims, the following summarizes the comments and the relevant workshop discussions, reviews the consumer perception evidence, and provides the Commission's analysis.

A. Sustainable Claims

1. Comments

Many commenters and workshop panelists addressed whether the Commission should revise the Guides to address sustainable claims. Commenters disagreed on the meaning of sustainable and whether the term could even be defined. Some argued the claim should be banned, while others asserted it could be used properly in certain contexts. Others observed that the term may be used to convey information about a company's environmental philosophies, independent of specific product claims.

Many commenters observed that the term "sustainable" has become part of the national vernacular.³⁴⁷ GMA, for example, cited a study finding that from September 2006 through December 2007, the use of the term on Internet blogs increased more than 100 percent.³⁴⁸

Several Packaging Workshop panelists noted that sustainable claims may embrace such diverse issues as child labor, community relations, economic development, and other non-environmental considerations.³⁴⁹ For example, the Sustainable Packaging Coalition's "vision" for sustainable packaging includes the aspiration that the packaging "benefits individuals and communities throughout its life cycle."³⁵⁰ Another commenter, the Center for Sustainable Innovation, broadly defined sustainability as "how an organization contributes, or aims to contribute in the future, to the improvement or deterioration of economic, environmental, and social conditions, developments, and trends at the local, regional, or global level."³⁵¹

Several commenters asserted that there is no clear understanding of the term, not just for the typical consumer, but among experts and business managers.³⁵² These commenters, however, disagreed regarding whether the FTC should attempt to define the specific attributes of sustainability. For example, some urged the FTC "to avoid tackling the onerous and possibly unachievable task of defining the specific attributes of sustainability."³⁵³ In contrast, others argued that the Guides should address the term.³⁵⁴ The Environmental Packaging Institute, for example, suggested that the term "sustainable" warrants the addition of a new section "complete with guidance, specific criteria, and examples."³⁵⁵

³⁴⁹ See, e.g., Dow, Comment 533431-00010 at 8; FPI, Comment 533431-00074 at 2; GMA, Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/tullier.pdf>); International Paper, Comment 533431-00055 at 8.

³⁵⁰ Anne Johnson, The Sustainable Packaging Coalition ("SPC"), Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/johnson.pdf>). SPC remarked that this definition is an "aspirational vision" rather than a standard. This definition includes packaging that, among other things, "is sourced, manufactured, transported, and recycled using renewable energy"; "is made from renewable or recycled source materials"; and "is made from materials healthy in all probable end of life scenarios." See SPC, Green Packaging Workshop Tr. at 127, 131.

³⁵¹ Center for Sustainable Innovation, Comment 534743-00003 at 2.

³⁵² EHS, Comment 534743-00011 at 1; EPI, Comment 533431-00063 at 4; GMA, Comment 533431-00045 at 9; Georgia-Pacific, Comment 533431-00007 at 8; GreenBlue, Comment 533431-00058 at 7; NAIMA, Comment 536013-00017 at 12-13; Saint-Gobain, Comment 533431-00037 at 12.

³⁵³ NAIMA, Comment 536013-00017 at 12-13; Saint-Gobain, Comment 533431-00037 at 12.

³⁵⁴ EPI, Comment 533431-00063 at 4; see also GMA, Comment 533431-00045 at 9 ("[T]he Guides should be updated to include a discussion of 'sustainable' claims and what constitutes a reasonable basis for substantiating such claims.").

³⁵⁵ EPI, Comment 533431-00063 at 4.

Because of the claim's expansiveness, several commenters likened the term "sustainable" to general environmental benefit claims.³⁵⁶ Thus, some of these commenters recommended that the Guides caution that the term "sustainable" be accompanied by language limiting its environmental superiority claim to the particular attribute, or attributes, that can be substantiated.³⁵⁷ Others suggested that marketers making sustainable claims should demonstrate that all aspects of a product's life cycle meet the criteria for sustainability.³⁵⁸ Some suggested that the FTC include new examples using the term "sustainable" in the general environmental benefit claim section of the Guides to clarify which sustainability claims may be deceptive.³⁵⁹

On the other hand, some commenters argued that the term "sustainable" simply should not be used as a marketing claim.³⁶⁰ The Sustainable

³⁵⁶ See 16 C.F.R. Part 260.7(a); see also BSR, Comment 533431-00016 at 1; P&G, Comment 533431-00070 at 2; SDA, Comment 534743-00028 at 1; SPI, Comment 533431-00036 at 5; Seventh Generation, Comment 533431-00033 at 5; Weyerhaeuser, Comment 533431-00086 at 1.

³⁵⁷ SDA, Comment 534743-00028 at 1-2; see also GMA, Comment 533431-00045 at 8-9 (recognizing complexity of measuring sustainability, but arguing for allowing such claims when qualified with a statement identifying environmental product attributes); ACC, Comment 533431-00023 at 8-9; Dow, Comment 533431-00010 at 10; Formaldehyde Council, Comment 533431-00047 at 5; Georgia-Pacific, Comment 533431-00007 at 8; Hammer, Comment 533431-00017 at 9; P&G, Comment 533431-00070 at 3; Seventh Generation, Comment 533431-00033 at 5; Vinyl Institute, Comment 533431-00046 at 3.

³⁵⁸ CSPA, Comment 533431-00049 at 3 (stating comparative sustainability claims "should have a clear basis for verification, such as certified life cycle assessment"); Rachel Chadderdon and Meghan Genovese, Comment 533431-00054 at 1 (arguing that, because no product can be fully sustainable unless all aspects of its life cycle meet the criteria for sustainability, marketers wishing to make environmental sustainability claims "must disclose exactly which components of the production cycle are and are not sustainable"); Stepan Company, Comment 533431-00011 at 2; Tandus, Comment 536013-00037 at 1.

³⁵⁹ Eastman, Comment 533431-00051 at 1 (suggesting the Guides define sustainability for marketing purposes and provide categories of industry practices and product properties that support this definition); GMA, Green Packaging Workshop Tr. at 143 (recommending the Guides include examples on how to qualify sustainability claims to "put [them] in the proper context"); EPI, Green Packaging Workshop Tr. at 210; GPI, Comment 534743-00026 at 10; USGBC, Comment 534743-00027 at 3.

³⁶⁰ See EHS, Comment 534743-00011 at 1 (stating that "sustainable" should not appear as a product or package descriptor because "[t]he term is ill-defined and made up of several factors, often specific to a particular product or manufacturer"); GreenBlue, Comment 533431-00058 at 7 ("We recommend strengthening the Guides to actively discourage companies from describing their products as . . . 'sustainable.'"); William Mankin,

³⁴⁵ GPI, Comment 534743-00026 at 8-9.

³⁴⁶ This guidance can now be found in 16 CFR 260.13.

³⁴⁷ See, e.g., Eastman, Comment 533431-00051 at 1 (stating that "sustainable" and "green" are the most "significant new additions" to the vocabulary describing the environmental benefits of products); Dow, Comment 533431-00010 at 9.

³⁴⁸ GMA, Green Packaging Workshop Tr. at 112; see also ACC, Green Packaging Workshop Tr. at 241; Weyerhaeuser, Comment 533431-00084 at 2.

Packaging Coalition (“SPC”), for example, stated that currently no accepted criteria with supporting test methods exists to qualify a package as sustainable.³⁶¹ According to SPC, the term “sustainable,” like the terms “green” or “environmentally friendly,” has no intrinsic meaning and confuses consumers, even if marketers qualified it with text that describes the specific attribute(s) that make their product sustainable.³⁶²

Some commenters noted that, because there are no definitive methods for measuring sustainability or confirming its accomplishment, the Green Guides should discourage statements claiming achievement of sustainability but permit general references to sustainability goals or processes.³⁶³ ACC, for example, recommended that the Guides clarify that “claims of a product or process *being* ‘sustainable’ are more properly characterized as that [the] product or process *promotes* or *contributes* to sustainability and/or sustainable outcomes, since sustainability is a process or a goal.”³⁶⁴ Weyerhaeuser noted that ISO 14021 prohibits claims of achieving sustainability, but that this prohibition does not apply to marketer’s statements about their “sustainability goals, processes, or aspirations.”³⁶⁵

Other commenters argued that the term “sustainable” can be used properly in specific contexts. The Sustainable Forestry Initiative (“SFI”), for example, stated that, in forestry, “sustainable” is a well-recognized concept that can be clearly and specifically defined.³⁶⁶ SFI

explained that it has a specific forest certification standard, the “SFI Standard,” which defines “sustainable forestry,” sets forth performance measures and indicators, and confirms compliance with a third-party certification audit. Thus, SFI proposed that the Guides state that a forest certification label may properly claim compliance with a specific forest certification standard and that a third-party audit verifying conformance with the standard is adequate substantiation.³⁶⁷

In contrast, commenter William Mankin argued that sustainable claims should not be used in any particular context, including forestry.³⁶⁸ In his view, it is difficult to attain sustainability in forests because forests are complex ecological systems. Moreover, he asserted that there is no widespread consensus on a definition of the term “sustainable,” particularly in fields involving the management of ecological systems and biological resources. He noted, for example, that in the field of forest management, some believe the term applies primarily to the ecological attributes of forests, while others believe it pertains more to social and economic concerns outside forests.³⁶⁹

Finally, some commenters observed that terms such as “sustainable” may be used independently from product claims to communicate important information about a company or organization’s mission and vision. For example, GMA referenced the following example of a company’s statement about its environmental efforts: “The General Mills Sustainability Initiative is a company-wide effort to responsibly manage the natural resource base our business depends on.”³⁷⁰ GMA argued that this is a broad statement about corporate philosophy rather than a claim made for specific products or services, and, therefore, should be

definition of sustainability may be adopted by the FTC, but . . . specific sectors should be able to develop focused definitions that meet the needs of that sector.”; Weyerhaeuser, Comment 534743-00033 at 1 (stating that a claim of “sustainable forestry” in the context of a forest certification system “provides consumers with specific, factual information and is not a broad claim”).

³⁶⁷ In support of its argument, SFI referenced the Canadian Competition Bureau’s analysis of ISO 140121, clause 5.5, “which prohibits general and undefined claims of sustainability, but permits claims that a seller conforms to a specific forest certification standard.” *Id.* at 5.

³⁶⁸ William Mankin, Comment 534743-00020 at 1; *see also* Caroline Pufalt, Comment 534743-00021 at 1.

³⁶⁹ *Id.*

³⁷⁰ GMA, Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/tullier.pdf>).

outside the scope of the Guides.³⁷¹ In addition, USGBC recommended that the FTC distinguish between “statements . . . which are used to convey broad organizational goals and should not require substantiation, and product claims, which make assertions about specific product attributes.”³⁷²

2. Consumer Perception Evidence

Commenters submitted limited consumer perception evidence regarding sustainable claims. Weyerhaeuser cited findings from its 2006 focus groups in four U.S. cities indicating that consumers were unable to define the term.³⁷³ Similarly, the National Cotton Council of America (“National Cotton Council”) described its own 2006 research, which found that only one third of consumers understand the term “sustainable” in the context of “sustainable agriculture.”³⁷⁴ It also cited a 2007 study by the Hartman Group finding that just over half of consumers claim any familiarity with the term “sustainability,” and most cannot define it “appropriately” upon probing.³⁷⁵ The National Cotton Council also provided the Commission with findings from a 2008 study indicating that 43 percent of respondents believed the term “sustainable” means “will last longer/good quality.”³⁷⁶

These results are consistent with the Commission’s consumer perception

³⁷¹ GMA, Comment 533431-00045 at 8 (citing as examples company website sections on environmental activities and discussions of activities in annual reports or other comparable communication vehicles); *see also* EHS, Comment 534743-00011 (asserting that companies should discuss their programs regarding sustainable development in a “full text document,” such as their website or in their “corporate sustainability report”); Georgia-Pacific, Comment 533431-00007 at 8 (recommending that the FTC discourage the unqualified use of “sustainable” for products and reserve it for “providing information about a company’s [environmental] indicators and overall improvement on those indicators in time”); PCPC, Comment 533431-00075 at 6 (recommending that the FTC maintain the Guides’ focus on products, packages, and services, not “general company practices”); SPI, Comment 533431-00036 at 4 (stating that businesses should be able to explain commitments and activities intended to advance “sustainability”).

³⁷² USGBC, Comment 534743-00027 at 3.

³⁷³ Weyerhaeuser, Comment 533431-00086 at 1.

³⁷⁴ National Cotton Council (“NCC”), Comment 536013-00027 at 4. This study is available at (<http://www.ftc.gov/green>). The NCC considered the following responses to be correct interpretations of “sustainable”: “minimum impact on environment” and “reuse or replenish land, use in future, doesn’t deplete.” E-mail from Cotton Incorporated (Mar. 11, 2010).

³⁷⁵ NCC, Comment 536013-00027 at 52. The commenter did not indicate what the Hartman Group considers the “appropriate” meaning of sustainable.

³⁷⁶ Cotton Incorporated, Lifestyle Monitor Survey, July 2008, available at (<http://www.ftc.gov/green>).

Comment 534743-00020 at 1 (stating that the FTC should prohibit use of the term “sustainable” and any claims related to the sustainability of a product in all on-product or off-product labels or claims); ILSR, Green Packaging Workshop Tr. at 144.

³⁶¹ SPC, Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/johnson.pdf>).

³⁶² *Id.* But *see* ACC, Comment 533431-00023 at 9 (asserting the Guides should cover sustainability claims because they can be appropriately qualified); AF&PA, Comment 533431-00083 at 3-4 (recommending the Guides allow use of “sustainable,” provided the marketer transparently communicates a reasonable basis for the claim; also noting that ISO is expecting to amend its current prohibition of the term due to growing experience and new consumer attitudes).

³⁶³ *See, e.g.*, CRI, Comment 533431-00026 at 1 (recommending the Guides distinguish between “sustainability (zero net impact) and environmental attributes (minimal net impact),” which contribute to sustainability); ACC, Comment 533431-00023 at 8; Weyerhaeuser, Comment 533431-00084 at 5-6.

³⁶⁴ ACC, Comment 533431-00023 at 8 (emphasis in original).

³⁶⁵ Weyerhaeuser, Comment 533431-00084 at 5. ISO 5.5 states that no claim of achieving sustainability shall be made because there are no definitive methods for measuring sustainability or confirming its accomplishment. ISO 14021 5.5:1999(E).

³⁶⁶ SFI, Comment 534743-00010 at 3-4; *see also* AF&PA, Comment 534743-00031 at 2 (“A broad

study. Specifically, in response to an open-ended question about the meaning of the term “sustainable,” some respondents stated the term means nothing (13 percent) or that they do not know what the term means (eight percent). Many others stated that it suggests a product is “strong/durable” (19 percent) or long-lasting (16 percent). Relatively few respondents indicated that the term “sustainable” was related to any particular environmental benefit,³⁷⁷ and only seven percent stated that the term suggested a product is “good for,” “helps,” or “benefits” the environment.³⁷⁸

In addition, responses to the closed-ended questions suggested that respondents did not view “sustainable” in the same way as a general environmental benefit claim. Specifically, respondents were less likely to believe that unqualified sustainable claims suggested specific, unstated environmental benefits than respondents who viewed “green” and “eco-friendly” claims. For example, while, on average, 52 percent of respondents viewing unqualified “green” claims, and 49 percent of respondents viewing “eco-friendly” claims, stated that these claims suggested that the product had several specific environmental attributes, only 17 percent of respondents viewing “sustainable” claims stated the product had these attributes.³⁷⁹ Moreover, while qualifying general environmental claims with a specific environmental attribute made respondents less likely to believe those claims suggested other, unstated environmental attributes, qualifying a “sustainable” claim did not have the same effect. Sixteen percent of respondents viewing an unqualified “sustainable” claim saw unstated environmental attributes, compared to 24 percent of respondents who saw such attributes when the claim was qualified with a specific environmental attribute.

3. Analysis

While marketers making sustainable claims may intend to convey that a product has general and/or specific environmental benefits, the consumer

³⁷⁷ Although 25 percent of respondents cited a specific environmental benefit, these responses were distributed over ten different environmental benefits (e.g., “made from recycled materials”; “recyclable”; “made with renewable materials”; “made from sustainable resources”).

³⁷⁸ In contrast, 27 percent of respondents viewing “green,” and 15 percent of respondents viewing “eco-friendly,” believed those claims suggested the product is “good for/helps/benefits the environment.”

³⁷⁹ These results were similar for all three tested products – kitchen flooring, laundry basket, and wrapping paper.

perception evidence indicates that the claim has no single environmental meaning to a significant number of consumers or that it conveys non-environmental characteristics (e.g., durable or long-lasting).³⁸⁰ In addition, the evidence indicates that consumers view sustainable claims differently than general environmental benefit claims.³⁸¹

The Commission, however, is unable to provide specific advice on sustainable as an environmental marketing claim. Unlike other claims we tested, the term contains no cue alerting consumers that it refers to the environment. If used in combination with environmental terms and images, consumers may perceive “sustainable” as an environmental claim. However, given the diversity of possible phrases and imagery, testing the claim in context was not practical. Therefore, the Commission lacks a sufficient basis to provide meaningful guidance on the use of sustainable as an environmental marketing term. Marketers, however, are responsible for substantiating consumers’ understanding of this claim in the context of their advertisements.

Some commenters noted that, to the extent the term “sustainable” is used to communicate information about a company’s environmental philosophy, such statements should be outside the scope of the Guides. Corporate image advertising raises First Amendment issues. The degree of constitutional protection provided to corporate image advertising is determined by the category of speech into which that expression falls. Therefore, as with all types of claims, the Commission evaluates each advertisement to determine whether it constitutes commercial speech. There is no clear standard for determining whether speech with elements of both commercial and non-commercial speech will be considered commercial, as opposed to non-commercial speech. Rather, the Supreme Court has assessed the totality of circumstances surrounding the expression to determine its character, including the content of the speech, whether the speaker’s motivation is economic, the audience to whom and the manner in which the speech is directed, and

³⁸⁰ Section 5 of the FTC Act does not require that an advertiser have intended to convey a deceptive claim. See *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 and n.5 (D.C. Cir. 1977); *Regina Corp. v. FTC*, 322 F.2d 765, 768 (3d Cir. 1963). Therefore, if, in the particular context in which it is presented, a sustainable claim implies to consumers that the product has non-environmental characteristics, marketers must substantiate this implied claim.

³⁸¹ Unlike the other tested claims, the term “sustainable,” on its face, did not suggest that the advertised product had environmental attributes.

whether its commercial and non-commercial component parts are inextricably intertwined.³⁸² Because the determination of an advertisement’s constitutional status must be conducted on a case-by-case basis, the issue is not appropriate for general guidance.

B. Organic and Natural Claims

The current Guides do not specifically address claims that products, packages, or services are organic or natural. Several commenters discussed these claims and recommended that the Commission provide guidance regarding their use.³⁸³ Below, the Commission discusses other federal agencies’ guidance concerning the terms “organic” and “natural,” summarizes the relevant comments, and analyzes the issues.

1. Overview – Guidance from Other Agencies

Other government agencies have provided guidance on the appropriate scope of organic and, to a lesser extent, natural claims.

a. Organic Claims

The USDA’s National Organic Program (“NOP”) regulates the term “organic” for agricultural products.³⁸⁴ Agricultural products that are sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic ingredients” must be produced and processed in accordance with NOP standards.³⁸⁵ Under these standards, organic agricultural products must be produced and handled without using prohibited methods or synthetic substances, except as specifically authorized on the National List of Allowed and Prohibited Substances.³⁸⁶ Operators who produce or handle such products must be certified by an NOP-accredited agent.³⁸⁷ Products that qualify as “100 percent organic” or “organic” may use the USDA’s organic seal on their packaging and in their advertisements.³⁸⁸

The USDA does not regulate organic claims for non-agricultural products. No other federal agencies provide specific guidance regarding organic claims for non-agricultural products.

³⁸² See generally *Riley v. Nat’l Fed’n of the Blind*, 487 U.S. 781, 795-96 (1988); *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 67 n.14 (1983).

³⁸³ EPA-EPPP, Comment 533431-00038 at 1, 5; SDA, Comment 533431-00020 at 3; Seventh Generation, Comment 533431-00033 at 3, 5; Terressentials, Comment 534743-00012 at 1-2.

³⁸⁴ See 7 CFR Part 205.

³⁸⁵ See 7 CFR 301.

³⁸⁶ See 7 CFR 205.105; 205.601-606.

³⁸⁷ See 7 CFR 205.100.

³⁸⁸ See 7 CFR 205.311.

b. Natural Claims

To the extent that federal agencies have defined, or administered statutes defining, “natural,” they have done so only in specific contexts. For example, the Textile Products Identification Act, which is administered by the Commission, defines “natural fiber” as “any fiber that exists as such in the natural state.” 15 U.S.C. § 70(c). The USDA has defined “natural” meat and poultry as “a product containing no artificial ingredient or added color” and which “is only minimally processed.”³⁸⁹ The FDA has defined “natural flavor or natural flavorings” as substances containing the flavoring constituents derived from specified items, such as spices, fruits, vegetables, herbs, plant materials, meat, seafood, and eggs.³⁹⁰ At least in part because of the difficulties in developing a definition of “natural” that would be appropriate in multiple contexts, both the FDA and the FTC have previously declined to establish a general definition.³⁹¹

The FDA, however, has employed an informal policy regarding the term “natural.”

Specifically, it:

has considered “natural” to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called “natural.”³⁹²

2. Comments

Several commenters stated that marketers increasingly employ organic and natural claims and recommended that the Commission provide guidance regarding their use.³⁹³ Most commenters focused on the use of these terms to describe textiles.³⁹⁴

³⁸⁹ USDA Food Safety and Inspection Service, Fact Sheet, Meat and Poultry Labeling Terms, available at (http://www.fsis.usda.gov/Fact_Sheets/). The fact sheet further notes that the “label must explain the use of the term ‘natural’ (such as - no added colorings or artificial ingredients; minimally processed).”

³⁹⁰ 21 CFR 101.22.

³⁹¹ See 58 FR 2407 (Jan. 6, 1993) (FDA declines to undertake rulemaking to define “natural”); 48 FR 23270 (May 24, 1983) (FTC terminates rulemaking that would have regulated natural food claims).

³⁹² 56 FR 60466 (Nov. 27, 1991).

³⁹³ EPA-EPPP, Comment 533431-00038 at 1, 5; SDA, Comment 533431-00020 at 3; Seventh Generation, Comment 533431-00033 at 3, 5; Terressentials, Comment 534743-00012 at 1-2.

³⁹⁴ In addition to textiles, one commenter asserted that many organic claims for personal care products may be misleading. Terressentials, Comment 534743-00012 at 1. That commenter stated that the USDA has issued a policy statement

a. Organic Claims

Several commenters recommended that the Commission provide guidance for organically labeled textiles.³⁹⁵ Some suggested that the Commission consult with the NOP to clarify guidance for organic claims for textiles.³⁹⁶ Many of these commenters also recommended that the Guides adopt NOP’s production standards for organic raw fibers.³⁹⁷ Other commenters suggested that marketers of products that contain any organic fiber should be able to make claims about the amount of organic fiber, as long as the organic content has been certified by a third party.³⁹⁸

Commenters noted that consumers may understand organic claims to refer to the manufacturing of the textile and not just its fabric content.³⁹⁹ The commenters differed, however, in their views regarding how to address this issue. Several recommended that the Guides reference the Global Organic Textile Standard (“GOTS”) for the processing and manufacturing of organic textile products.⁴⁰⁰ One

permitting companies selling personal care products to apply for organic certification under the NOP, but many companies are making organic claims for personal care products without obtaining certification. *Id.* The commenter argued that many consumers mistakenly believe that such products comply with NOP standards. *Id.* On March 12, 2010, Consumers Union and the Organic Consumers Association filed a petition raising this concern and asking the Commission to investigate the use of organic claims for personal care products. The Commission has placed the petition on the record.

³⁹⁵ Better for Babies, Comment 536013-00033 at 1; ECONscious, Comment 536013-00023 at 1-2; International Sleep Products Association (“ISPA”), Comment 536013-00015 at 1; OMI, Comment 536013-00022 at 2-3; Organic Exchange, Comment 536013-00032 at 3-4; Organic Trade Association (“OTA”), Comment 536013-00016 at 1.

³⁹⁶ Better for Babies, Comment 536013-00033 at 1-2; ECONscious, Comment 536013-00023 at 2; OTA, Comment 536013-00016 at 2.

³⁹⁷ Better for Babies, Comment 536013-00033 at 1-2; ECONscious, Comment 536013-00023 at 1; OTA, Comment 536013-00016 at 1; Harmony Susalla (“Susalla”), Comment 536013-00028 at 1.

³⁹⁸ Organic Exchange, Comment 536013-00032 at 3; Texas Organic Cotton Marketing Cooperative (“TOCMC”), Comment 536013-00014 at 2.

³⁹⁹ See, e.g., OTA, Comment 536013-00016 at 2. The NOP standards apply only to the raw fibers; they do not cover the processing and manufacturing of textile products.

⁴⁰⁰ Better for Babies, Comment 536013-00033 at 2; ECONscious, Comment 536013-00023 at 2; OMI, Comment 536013-00022 at 4; OTA, Comment 536013-00016 at 4; Susalla, Comment 536013-00028 at 1-2; TOCMC, Comment 536013-00014 at 2. One commenter recommended that the Guides consider GOTS, as well as other processing standards such as Oeko-Tex and Bluesign. Organic Exchange, Comment 536013-00032 at 4. That commenter asserted that third-party organic certification should be recognized as substantiation for an organic claim. *Id.* Another commenter, however, expressed concern that references to the Oeko-Tex certification process may be misleading if the marketer does not disclose which Oeko-Tex

commenter noted, however, that GOTS is a “process review standard” that “leaves too many opportunities for mistakes and fraud within the dyeing and finishing process for textiles.”⁴⁰¹ That commenter stated there is a need for analytical verification to determine the presence of various chemicals in textile products.⁴⁰² Another commenter recommended that marketers disclose a complete list of ingredients when they make organic claims.⁴⁰³

Several commenters discussed whether marketers should be permitted to claim that fibers are “transitional organic” fibers. The USDA requires that to be certified as organic, fibers must be grown without chemical fertilizers, defoliants, or pesticides for three years. The term “transitional organic” refers to fiber grown according to these guidelines that has not yet met the three-year requirement. One commenter noted that some retailers are selling products containing “transitional cotton,” despite the fact that USDA does not recognize that term.⁴⁰⁴ Other commenters recommended that the Guides permit marketers to make “transitional organic” claims “to enable the organic fiber marketplace to grow while supporting the farmer during the three-year transition period.”⁴⁰⁵

One commenter indicated that numerous retailers appear to be marketing products made with conventional cotton as organic.⁴⁰⁶ That commenter also reported that retailers are making claims that products are certified organic but are not providing information about the certification.⁴⁰⁷ The commenter stated that research indicates consumers are confused about the meaning of organic claims and do not trust that products labeled as organic are, in fact, organic.⁴⁰⁸

b. Natural Claims

Several commenters stated that the term “natural” does not have a clear

certification process it is using. Susalla, Comment 536013-00028 at 2.

⁴⁰¹ Oeko-Tex, Comment 536013-00013 at 4.

⁴⁰² *Id.*

⁴⁰³ OMI, Comment 536013-00022 at 2.

⁴⁰⁴ NCC, Comment 536013-00027 at 2.

⁴⁰⁵ Organic Exchange, Comment 536013-00032 at 4; TOCMC, Comment 536013-00014 at 2. The Organic Exchange noted that the proof for a transitional claim would be that the farm has applied for organic certification, an initial on-site inspection has been conducted, and the farm has an organic system plan which includes the last date of use of prohibited substances. Organic Exchange, Comment 536013-00032 at 4.

⁴⁰⁶ NCC, Comment 536013-00027 at 3.

⁴⁰⁷ *Id.* The NOP regulations require that the products labeled as “100 percent organic” or “organic” must identify the agent that certified the products as organic. 7 CFR 205.303.

⁴⁰⁸ *Id.* at 4.

meaning.⁴⁰⁹ One commenter explained that natural claims for textiles are unclear because the products have “undergone significant transformation from the raw materials” they contain.⁴¹⁰ Another asserted that the term is meaningless and is used to exaggerate the environmental benefits of a product.⁴¹¹ One commenter, however, stated that consumers may understand the term given the context in which it is used.⁴¹²

The commenters discussed whether the Guides should address the term “natural.” Several recommended generally that the Guides address or define the term, but did not specify how the Guides should do so.⁴¹³ Some commenters suggested that natural may be appropriately used to distinguish between textiles derived from agricultural products and those derived from petrochemicals.⁴¹⁴ Another commenter recommended that the Guides advise marketers to substantiate natural claims with third-party verification or independent testing.⁴¹⁵

Others recommended that the Guides not allow the use of the term. For example, one commenter stated that because the term lacks a clear meaning in the textile sector, the Commission should not allow marketers to use it.⁴¹⁶ Another suggested that the Guides not allow natural claims even for fibers

⁴⁰⁹ EONscious, Comment 536013-00023 at 1; OTA, Comment 536013-00016 at 2; Oeko-Tex, Comment 536013-00013 at 5; Susalla, Comment 536013-00028 at 1.

⁴¹⁰ OTA, Comment 536013-00016 at 2 (stating also that the term “natural” “has only rarely been used as a term of art . . . by any U.S. regulatory agency”).

⁴¹¹ Susalla, Comment 536013-00028 at 1.

⁴¹² Tetra Pak, Comment 536013-00012 at 3. The commenter provided an example of the use of natural in context. It stated that claiming a product is “made from trees, a natural and renewable resource,” would not be deceptive if the product is made entirely using that material.

⁴¹³ ISPA, Comment 536013-00015 at 1 (proposing that the Commission establish objective criteria regarding when natural may be used as well as documentation required to substantiate the claim); SDA, Comment 536013-00018 at 1 (stating that natural claims for all products should be specific and verifiable); Susalla, Comment 536013-00028 at 1; Tandus, Comment 536013-00037 at 1; Tetra Pak, Comment 536013-00012 at 3.

⁴¹⁴ Better for Babies, Comment 536013-00033 at 2; NCC, Comment 536013-00027 at 2; OTA, Comment 536013-00016 at 2.

⁴¹⁵ TOCMC, Comment 536013-00014 at 1; *see also* OMI, Comment 536013-00022 at 3 (stating that if the Commission decides to address natural claims, a clear definition is required); Oeko-Tex, Comment 536013-00013 at 5 (stating that marketers should substantiate natural claims with specific, science-based definitions); Susalla, Comment 536013-00028 at 1 (stating that the Cotton Incorporated “green” message is deceptive because although U.S. cotton is grown on less land and with fewer chemicals, this is not the case with farms around the world).

⁴¹⁶ EONscious, Comment 536013-00023 at 1.

grown agriculturally because agriculture can have a negative impact on the environment, such as water and air pollution and soil erosion.⁴¹⁷

3. Consumer Perception Evidence

Only one commenter, the National Cotton Council, cited consumer perception evidence regarding organic claims. It asserted that its research indicates that consumers are confused about these claims, with more than two-thirds of respondents either believing, or not sure, if organic cotton textiles were made from recycled materials or contain soy.⁴¹⁸ The research also indicated that consumers do not trust that products labeled as organic are, in fact, organic.⁴¹⁹

No commenters provided consumer perception evidence indicating how consumers understand the term “natural.”

4. Analysis

The Commission does not propose creating a new section of the Guides to address organic and natural claims. The explanation for this decision is discussed below separately for each claim.

Although the Commission is not proposing a new section for these claims, the general principles set forth in the Guides still apply. Marketers must have substantiation for their environmental benefit claims, including implied claims.⁴²⁰ More specifically, to the extent that reasonable consumers perceive organic or natural claims as general environmental benefit claims or comparative claims, the marketer must be able to substantiate those claims and all other reasonably implied claims, as described in Part V.A.4 above.⁴²¹

a. Organic Claims

The Commission does not propose addressing organic claims for two reasons. First, the NOP already addresses organic claims for agricultural products. Second, for products that are outside the NOP’s jurisdiction, the current record is insufficient for the Commission to provide specific guidance.

⁴¹⁷ Todd Copeland, Patagonia, Comment 536013-00011 at 1; *see also* REI, Comment 536013-00031 at 1 (stating that the Commission should be mindful that agriculture can have a significant impact on the environment).

⁴¹⁸ NCC Comment 536013-00027 at 4 (citing 2003 and 2006 studies conducted jointly with the OTA).

⁴¹⁹ *Id.*

⁴²⁰ 16 CFR 260.5.

⁴²¹ 16 CFR 260.6(d), 260.7(a).

i. Organic Claims for Agricultural Products

As described above, the NOP provides a comprehensive regulatory framework governing organic claims for agricultural products. Because of this framework and the NOP’s ongoing work in this area, the Commission does not want to propose duplicative or possibly inconsistent advice. Therefore, the Commission declines to address organic claims covered by NOP standards in the Guides.⁴²²

For the same reason, the Commission does not propose addressing standards for processing organic textiles. The USDA has indicated that organic claims for finished textile products fall within its jurisdiction. Following the Commission’s Green Building and Textiles Workshop, the NOP released a new fact sheet, “Labeling of Textiles Under National Organic Program (NOP) Regulations,” which discussed organic claims regarding textiles.⁴²³ Therefore, rather than proposing duplicative or potentially inconsistent advice, Commission staff will continue to consult with NOP staff to ensure that marketers have sufficient guidance regarding organic claims for textile products.

ii. Organic Claims for Non-agricultural Products

Although the NOP’s regulatory framework governs organic claims for agricultural products, it does not apply to organic claims for non-agricultural products. Therefore, within a particular category (e.g., cosmetics), some products are covered by NOP standards and other products are not, depending on their ingredients.⁴²⁴ Yet, both products could be advertised as organic. It is unclear how consumers understand organic

⁴²² Although some commenters recommended that the Guides endorse “transitional organic” claims for fibers, it is unlikely consumers would understand the meaning of this term and the issue is more appropriately addressed by the NOP.

⁴²³ USDA Labeling of Textiles Under National Organic Program (NOP) Regulations Fact Sheet, July 2008, available at (<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5070818&acct=nopgeninfo>).

⁴²⁴ Cosmetics, body care products, and personal care products illustrate this difference. The USDA has stated that if these products contain agricultural ingredients and can satisfy NOP organic production, handling, processing, and labeling standards, they are eligible for certification under NOP regulations. However, the USDA has stated that it does not have authority over the production and labeling of such products if they do not contain agricultural ingredients or do not make any claim that they meet USDA organic standards. USDA Cosmetics, Body Care Products and Personal Care Products Fact Sheet, April 2008, available at (<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5068442&acct=nopgeninfo>).

claims that describe non-agricultural products, and how marketers of those products substantiate their claims.

No commenters submitted consumer perception evidence on this issue. The Commission, therefore, lacks a basis to provide guidance on the use of organic claims for products outside NOP's jurisdiction. Accordingly, the Commission requests comment on what guidance, if any, it should provide regarding the use of organic claims to describe non-agricultural products.

b. Natural Claims

The Commission also does not propose addressing natural claims. As discussed above, the role of the Guides is to prevent consumer deception, so definitions for terms such as natural must be based on what consumers understand those terms to mean. However, no commenters provided consumer perception evidence indicating how consumers understand the term "natural." In addition, natural may be used in numerous contexts and may convey different meanings depending on that context.⁴²⁵ Thus, the Commission does not have a basis to provide general guidance on the use of the term.

Some commenters recommended that the Guides prohibit the use of natural claims. In evaluating whether a representation is misleading, the Commission examines not only the claim itself, but the net impression of the entire advertisement.⁴²⁶ Thus, in order to state that marketers should never use the term "natural," the Commission would have to conclude that the use of the term is deceptive in every context and that no reasonable qualification is sufficient to prevent that deception. In the absence of evidence demonstrating that natural is always deceptive and that its use could not be qualified to avoid such deception, the Commission cannot prohibit marketers from using the term. Moreover, as noted above, several agencies, including the FTC, the FDA, and the USDA, acknowledge that natural may be an appropriate descriptor in some contexts.⁴²⁷

⁴²⁵ As noted above, the FTC and the FDA have previously declined to adopt a wide-ranging, formal definition of "natural."

⁴²⁶ Deception Policy Statement, 103 F.T.C. at 179 (when evaluating representations under a deception analysis, one looks at the complete advertisement and formulates opinions "on the basis of the net general impression conveyed by them and not on isolated excerpts"). Depending on the specific circumstances, qualifying disclosures may or may not cure otherwise deceptive messages. *Id.* at 180-81.

⁴²⁷ See Part VI.B.1.b, *supra*.

Marketers that are using terms such as natural must ensure that they can substantiate whatever claims they are conveying to reasonable consumers. If reasonable consumers could interpret a natural claim as representing that a product contains no artificial ingredients, then the marketer must be able to substantiate that fact. Similarly, if, in a given context, a natural claim is perceived by reasonable consumers as a general environmental benefit claim or as a comparative claim (*e.g.*, that the product is superior to a product with synthetic ingredients), then the marketer must be able to substantiate that claim and all attendant reasonably implied claims.⁴²⁸

C. Renewable Materials Claims

Although the Commission solicited comments on whether the Guides should be revised generally to include renewable claims, the vast majority of commenters addressed this term in the context of "renewable materials"⁴²⁹ or "renewable energy."⁴³⁰ Therefore, the Commission has focused on these two types of renewable claims. This part discusses comments, relevant consumer perception evidence, and the Commission's proposed guidance for renewable materials claims. Part VI.D, below, addresses renewable energy claims.

1. Comments

Comments addressed the following issues: (1) use of an unqualified renewable claim; (2) the elements of a renewable materials claim, including the time frame under which material must be renewed; (3) the quantity of renewable materials in a product or package marked "made with renewable materials"; (4) the specific substantiation for a renewable materials claim; and (5) consumer confusion between renewable materials claims and biodegradability.

a. Unqualified Renewable Claims

Two commenters recommended that the Guides clarify that "the characteristic of 'renewable' must be ascribed to a material or fuel," and not to the product or package itself.⁴³¹

⁴²⁸ See Part V.A.4, *supra*.

⁴²⁹ Although commenters also referred to "renewable resources," the Commission uses the term "materials" for consistency.

⁴³⁰ According to the FTC Staff Internet Surf, among renewability claims, the phrases "renewable energy" and "renewable resource" occurred most frequently. "Renewable energy" occurred in 46 percent of the 387 web pages containing renewable claims, and "renewable resource" occurred in 37 percent.

⁴³¹ FBA, Comment 533431-00015 at 4; Georgia-Pacific, Comment 533431-00007 at 8.

According to these commenters, "it is not proper to ask if [a product] is renewable but rather if the material composing it in a majority by weight is renewable."⁴³² A third commenter asserted that a product labeled with an unqualified renewable claim is deceptive because it does not provide consumers with information that can be used to evaluate the claim.⁴³³

b. Elements of Renewable Materials Claims

Most commenters did not offer evidence or views on how consumers perceive renewable materials claims.⁴³⁴ Rather, they suggested definitions for the term. For example, two commenters defined renewable materials as materials having "the capacity of being regenerated either through natural processes or with human assistance, for example, through replanting with nursery seedlings or natural reseeding."⁴³⁵ Another stated that renewable materials are "capable of being replaced by natural ecological cycles or sound management practices."⁴³⁶

Commenters, however, argued that there is an ongoing debate regarding the definition of "renewable" and strongly urged the Commission to "approach renewability broadly and recognize that there is no consensus on what should be treated as a renewable resource."⁴³⁷ Moreover, although some commenters observed that renewable materials include biobased products,⁴³⁸ one commenter remarked that defining renewable materials to include only agriculturally based materials is too limiting.⁴³⁹ According to this commenter, although not agriculturally based, sand is a renewable resource because deposits are increased daily "by the normal, ongoing geological processes that generate new deposits of sand in the hundreds of millions of tons each year."⁴⁴⁰

Another commenter provided a more detailed definition. According to this

⁴³² *Id.*

⁴³³ ACC, Comment 533431-00023 at 11 (suggesting that a product labeled, for example, "uses 20% renewable feedstock" would not be deceptive).

⁴³⁴ In fact, only one commenter, the National Cotton Council, cited consumer perception evidence. NCC, Comment 536013-00027 at 4; See Part VI.C.2, *infra*.

⁴³⁵ AF&PA, Comment 533431-00083 at 4; *see also* FBA, Comment 533431-00015 at 4.

⁴³⁶ NCC, Comment 536013-00027 at 1.

⁴³⁷ NAIMA, Comment 536013-00017 at 14; Saint-Gobain, Comment 533431-00037 at 13.

⁴³⁸ See, *e.g.*, Dow, Comment 533431-00010 at 15; GreenBlue, Comment 533431-00058 at 7.

⁴³⁹ NAIMA, Comment 536013-00017 at 14.

⁴⁴⁰ *Id.*; *see also* FBA, Comment 533431-00015 at 4; Georgia-Pacific, Comment 533431-00007 at 8.

commenter, a material is renewable if: (1) the rate of the material's replenishment matches the rate of consumption; (2) the sourcing of the material does not harm the ecosystem or negatively impact "sustainability"; (3) sourcing of the material reduces consumption of non-renewable resources; and (4) use of the renewable material does not "significantly increase the product's environmental footprint in other relevant indicators (e.g., water, waste, energy, etc.)."⁴⁴¹ Along these lines, other commenters stated that renewability claims may deceive consumers if the beneficial attributes associated with the renewable materials do not account for every environmental trade-off, after analyzing the entire life cycle of the source.⁴⁴²

Other commenters suggested that renewable materials claims may convey some broader environmental benefit.⁴⁴³ In particular, one commenter cautioned that advertisers should be careful not to equate such claims with an overall environmental benefit, observing, for example, that although ethanol may be renewable, its overall environmental benefit is debated because of "the large amount of energy needed to create it (and the carbon emissions that its creation entails)."⁴⁴⁴

In contrast, another commenter stated that consumers understand renewability to refer to only one attribute (i.e., the biological properties of a material) and do not interpret renewability claims to imply that "there are no other environmental issues."⁴⁴⁵ Thus, this commenter urged the FTC not to expand renewability "beyond a simple biological claim."⁴⁴⁶

Some commenters specifically addressed whether and how the Guides should address time frames for renewability. One commenter, for example, suggested that the Guides provide that the time frame within which a resource is renewed is "commensurate with the rate of its use and that the appropriate management practices are used to ensure a material's renewability."⁴⁴⁷ This commenter explained that the term "begs the question 'On what time scale?'" The argument can be made that everything is

renewable in geologic time or that products are renewable if fossilization is included in the life cycle."⁴⁴⁸ Others similarly asked the FTC to provide specific time frames for renewability.⁴⁴⁹

c. Quantity of Renewable Materials

Several commenters addressed the question of how much of a product should be renewable for a marketer to make an unqualified "made with renewable materials" claim. Some recommended that the FTC use its current guidance on recyclability and recycled content as a model, i.e., a renewable claim could be made only if an entire product or package, excluding minor incidental components, is made of renewable materials.⁴⁵⁰ Otherwise, the marketer should qualify the renewability claim by stating the percentage of renewable materials.

Other commenters presented slightly differing views. The Biodegradable Products Institute ("BPI," for example, recommended a more specific cut-off, asserting that marketers make unqualified "made with renewable materials" claims only for products that have greater than 95 percent non-petroleum resources.⁴⁵¹ In contrast, two commenters argued that marketers should be able to make an unqualified claim if a "majority" of the product consists of renewable materials.⁴⁵²

In addition to recommending a threshold for an unqualified claim, some commenters suggested that marketers' promotional materials should provide specific information about the renewable material, such as the exact percentage of renewable materials in a product⁴⁵³ or the source of specific raw materials used.⁴⁵⁴

⁴⁴⁸ *Id.*

⁴⁴⁹ CRI, Comment 533431-00026 at 2 (stating that the FTC should define applicable time frames but not recommending specific time frames); Georgia-Pacific, Comment 533431-00007 at 4 (same); Tandus, Comment 536013-00037 at 1 (suggesting, as an example, a 10-year time frame).

⁴⁵⁰ ACC, Comment 533431-00023 at 11; *see also* SPI, Comment 533431-00036 at 6 (recommending that the FTC address situations where less than 100 percent of contents are "renewable"; could take approach similar to guidance on products containing less than 100 percent recycled content); Stepan Company, Comment 533431-00011 at 3.

⁴⁵¹ Steve Mojo, Biodegradable Products Institute ("BPI"), Green Packaging Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/packaging/presentations/mojo.pdf>) (recommending that products containing less than 95 percent renewable content should state that percentage).

⁴⁵² FBA, Comment 533431-00015 at 4; Georgia-Pacific, Comment 533431-00007 at 6, 8.

⁴⁵³ ACC, Comment 533431-00023 at 11; *see also* Hammer, Comment 533431-00017 at 8 (stating marketers should specify the percentage of the total product that is renewable).

⁴⁵⁴ SPI, Comment 533431-00036 at 6.

d. Substantiating Renewable Materials Claims

Some commenters suggested that the Guides specifically address the procedures needed to substantiate renewable and biobased claims. For example, one commenter suggested that the Guides recommend either self-certification with publicly available documentation using EPA definitions or a third-party certification.⁴⁵⁵ Others opined that the Green Guides specify the methods used to determine biocontent.⁴⁵⁶ For example, some commenters suggested ASTM D 6866⁴⁵⁷ could be used to accurately determine the percentage of the product that comes from renewable resources.⁴⁵⁸

e. Confusion Between Renewable Materials Claims and Biodegradability

Two commenters noted that consumers may mistakenly believe that products labeled "made with renewable materials" are also biodegradable.⁴⁵⁹ Specifically, BPI cited a study conducted by APCO Insight in 2006 finding that 80 percent of consumers believe that a package made from natural materials, such as corn-based plastics, were more likely to be biodegradable than a package made from synthetic materials.⁴⁶⁰ However, some biobased products, such as products made from sugar cane, contain non-degradable polymers.⁴⁶¹ Moreover, according to the Institute for Local Self-Reliance, some of the plastics on the market that meet biodegradability standards contain no plant matter.⁴⁶² To address this confusion, BPI recommended that the Guides make clear that naturally based materials may, or may not, be compostable or biodegradable.⁴⁶³

⁴⁵⁵ CRI, Comment 533431-00026 at 2.

⁴⁵⁶ BPI, Green Packaging Workshop Tr. at 90-91; Georgia-Pacific, Comment 533431-00007 at 8; ILSR, Green Packaging Workshop Tr. at 136-138; Stepan Company, Comment 533431-00011 at 2.

⁴⁵⁷ ASTM D 6866 "Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis."

⁴⁵⁸ BPI, Green Packaging Workshop Tr. at 83; Georgia-Pacific, Comment 533431-00007 at 8; ILSR, Green Packaging Workshop Tr. at 136-138.

⁴⁵⁹ BPI, Green Packaging Workshop Tr. at 89 and (<http://www.ftc.gov/bcp/workshops/packaging/presentations/mojo.pdf>).

⁴⁶⁰ *See* APCO, Biodegradable and Compostable Survey Topline at 4.

⁴⁶¹ *Id.*; ILSR, Green Packaging Workshop Tr. at 137-138.

⁴⁶² ILSR, Green Packaging Workshop Tr. at 137-138.

⁴⁶³ BPI, Green Packaging Workshop Tr. at 102-103.

⁴⁴¹ P&G, Comment 533431-00070 at 3. This commenter's remarks also applied to renewable energy.

⁴⁴² Seventh Generation, Comment 533431-00033 at 5 (stating the attribute should cover the entire life cycle of the source so as to account for any trade-off); SDA, Comment 533431-00020 at 4.

⁴⁴³ SPI, Comment 533431-00036 at 6.

⁴⁴⁴ Hammer, Comment 533431-00017 at 9.

⁴⁴⁵ Weyerhaeuser, Comment 533431-00084 at 6.

⁴⁴⁶ *Id.*

⁴⁴⁷ GreenBlue, Comment 533431-00058 at 7.

2. Consumer Perception Evidence

As noted above, one commenter, the National Cotton Council, described a finding from its 2006 telephone/Internet study that “only one third of consumers correctly understand the term . . . ‘renewable’” when referring to cotton.⁴⁶⁴

The Commission’s consumer perception study tested respondents’ understanding of the phrase “made with renewable materials” as this claim appeared on three different products – wrapping paper, a laundry basket, and kitchen flooring. The study results indicated that, for all products, respondents thought this claim definitely or probably suggested that the product had other environmental attributes. For example, 53 percent believed that this phrase suggested that the product was recyclable.⁴⁶⁵ In addition, 45 percent believed the phrase suggested that the product was made from recycled materials. Fewer, but still a significant number, believed that a “made with renewable materials” claim suggested that the product was biodegradable (28 percent), compostable (24 percent), and made with renewable energy (23 percent).

Responses to the open-ended question “[w]hat, if anything, does this statement suggest or imply to you about the product,” confirmed these results. For all three tested products, a significant number said that the product was made from recycled materials (31 percent) or materials that can be recycled (17 percent).

A smaller number of respondents answering the open-ended questions perceived the claim in the same way as marketers appear to intend. Specifically, 10 percent stated the term implied that materials could be replenished, replaced, or regrown; 4 percent stated the materials were derived from plant matter; 0.4 percent suggested the materials were non-petroleum based; and 0.6 percent indicated the materials could be grown quickly.⁴⁶⁶

The study further tested what a “made with renewable materials” claim conveyed about the percentage of renewable materials in a product. Specifically, the study asked

⁴⁶⁴ NCC, Comment 536013-00017 at 4. This study, which Cotton Incorporated conducted, is available at (<http://www.ftc.gov/green>). The NCC counted the terms “recycled,” “reused/regrown,” and “sustainable for environment” as “correct” interpretations of the term. E-mail from Cotton Incorporated (Mar. 11, 2010).

⁴⁶⁵ This and the following numbers are net of the non-environmental control claim.

⁴⁶⁶ These findings are based on FTC staff’s more detailed analysis of the open-ended responses rather than Harris’ general findings.

respondents whether a statement that a product is “made with renewable materials” suggests that all, most, or some of the materials were renewable. In response, 37 percent indicated that they would interpret the claim to mean that “all” of the materials were renewable, and an additional 20 percent believed that the claim meant “most.”⁴⁶⁷

3. Analysis and Guidance

To avoid deception, the Commission proposes advising marketers to qualify a “made with renewable materials” claim with specific information about the material.⁴⁶⁸ In addition, marketers should qualify this claim for products containing less than 100 percent renewable materials, excluding minor, incidental components. The Commission does not propose defining the term or endorsing any particular test to substantiate such claims.

a. Qualifying Renewable Materials Claims

Rather than providing a technical or scientific definition for environmental claims, the Guides state what consumers understand the claims to mean. The results of the Commission’s consumer perception study suggest there is a disconnect between consumer understanding of “made with renewable materials” claims and what marketers appear to intend to convey. Marketers, for example, may intend to communicate that a product is made from a material that can be replenished at the same rate, or faster, than consumption.⁴⁶⁹ Consumers, however, likely believe the product has other specific environmental benefits, such as being made with recycled content, recyclable material, and biodegradable material. The Commission, therefore, proposes advising marketers to qualify “made with renewable materials” claims to avoid misleading consumers.

While the Commission did not test particular qualifiers, it nevertheless believes that providing specific information about the renewable material may correct consumers’ misimpressions about this claim. For

⁴⁶⁷ Further, 26 percent stated that “some” of the product was made with renewable materials; 13 percent stated that the claim does not suggest anything about how much of the product was made with renewable materials; and six percent stated that they were not sure. The figures total 102 percent because of rounding. These percentages were derived by combining the responses to all claims that included “made with renewable materials” (*i.e.*, “made with renewable materials,” “green - made with renewable materials,” “eco-friendly - made with renewable materials,” and “sustainable - made with renewable materials”).

⁴⁶⁸ This proposed guidance can be found in 16 CFR 260.15.

⁴⁶⁹ See, e.g., P&G, Comment 533431-00070 at 3.

example, providing information regarding which renewable materials were used, how the materials were sourced, and why the materials are renewable may align consumer perception with what marketers are trying to convey. Accordingly, in proposed Example 1, the Commission states that a “made with renewable materials” claim is unlikely to be deceptive if the marketer provides specific information about the material it uses (bamboo), how it sources the material (it grows the bamboo), and why it is renewable (the bamboo grows at a rate comparable or faster than its use). Providing this information should reduce confusion by providing context for the claim. The Commission seeks comment on whether providing this information, as in proposed Example 1, adequately qualifies a “made with renewable materials” claim.

b. Quantity of Renewable Materials

As noted above, a significant percentage of respondents (37 percent) indicated that they would interpret a “made with renewable materials” claim to mean that “all” of the materials in a product are renewable. Based on this result, the Commission proposes that, unless the entire product or package, excluding minor, incidental components, is made from renewable materials, marketers need to qualify the claim to specify the amount of renewable materials in a product or package. Thus, as illustrated in proposed Example 2, a marketer’s “made with renewable materials” claim would not be deceptive if it clearly states that its product, made from a blend of 50 percent petroleum-based plastic and 50 percent plant-based plastic, contains 50 percent renewable material. This proposed guidance is consistent with many of the commenters’ views and is modeled on the Commission’s current recycled content guidance.⁴⁷⁰

c. Substantiating Renewable Materials Claims

As discussed above, several commenters suggested that the Commission reference ASTM Method D 6866 as a means to substantiate “made with renewable material” claims. Although this protocol may determine the biobased content of natural

⁴⁷⁰ The Guides currently provide that unqualified claims of recycled content may be made if the entire product or package (excluding minor, incidental components) is made from recycled content. 16 CFR 260.7(e). The recyclable section of the current Guides also contains similar language: “Unqualified claims of recyclability for a product or package may be made if the entire product or package, excluding minor incidental components, is recyclable.” 16 CFR 260.7(d).

materials, it does not necessarily substantiate all claims that consumers reasonably infer. Therefore, the Commission declines to reference it in the Guides as acceptable substantiation for renewable materials claims.

Proposed Example 3 illustrates this point. In this example, although the marketer used test results to determine that its product consists entirely of biological material, the marketer cannot substantiate other consumer interpretations of its unqualified “made with renewable materials” claim, including that the product is recyclable, made with recycled content, or biodegradable.

d. Biobased Claims

Some commenters used the term “biobased” interchangeably with the phrase “renewable material.”⁴⁷¹ It is not clear whether consumers interpret this claim in the same way as “renewable.” At this time, the Commission does not propose addressing biobased claims in the Guides because the USDA is conducting its own consumer perception study of biobased claims as part of its proposed voluntary labeling program for biobased products.⁴⁷² In developing this program, USDA has sought public comment on a proposed “USDA Certified Biobased Product” logo, which will include a statement that identifies the biobased⁴⁷³ content of the product and that indicates whether the label applies to the product or packaging (e.g., “Product: 57% biobased; Packaging: 90% biobased”). The USDA proposes that marketers determine biobased content by testing products pursuant to the ASTM Method D 6866 standard. Given USDA’s ongoing work in this area, the Commission does not want to propose duplicative or potentially inconsistent advice. Therefore, the Commission has decided not to address this issue in the Guides at this time.

D. Renewable Energy Claims

This section discusses claims about the sale of renewable energy as well as claims that a product is “made with renewable energy.” Specifically, the Commission discusses the ways renewable energy is sold, comments

addressing renewable energy claims, relevant consumer perception research, and the Commission’s analysis of the issues.

1. Overview

Renewable energy generally refers to electricity derived from constantly replenished sources (e.g., wind power).⁴⁷⁴ Once renewable electricity is introduced into the grid, it is physically indistinguishable from electricity generated from conventional sources. Consumers, therefore, cannot determine for themselves the source of the electricity flowing into their homes. Because electricity transactions can be tracked, however, retail customers can “buy” renewable power by either: (1) purchasing renewable energy certificates (RECs)⁴⁷⁵; or (2) purchasing renewable power through contracts with their utility.

Under the REC method, a renewable electricity generator splits its output into two components: (1) the electricity itself; and (2) certificates representing the renewable attributes of that electricity.⁴⁷⁶ Specifically, generators that produce renewable electricity sell their electricity at market prices for conventionally produced power and then sell the renewable attributes of that electricity through separate certificates.⁴⁷⁷ Organizations purchase RECs to characterize all or a portion of their electricity usage as “renewable” by matching the certificates with the conventionally produced electricity they normally purchase.⁴⁷⁸

Under the contract method, consumers and businesses purchase

renewable energy through traditional electricity contracts with their local utility or power provider.⁴⁷⁹ Energy sold through these “green power pricing” programs generally costs more than conventional energy. Utilities (or other electricity retailers) can obtain the renewable energy they sell through different means. Some generate renewable energy themselves and sell it to their customers. Others contract with renewable energy generators to purchase electricity, which utilities then sell to their customers. Additionally, some utilities purchase RECs to match their own conventionally produced energy so that they can characterize the energy they sell as renewable.⁴⁸⁰

Many businesses tout their renewable energy purchases to market their products or services.⁴⁸¹ For example, a clothing company may claim that its garments are “made with renewable energy,” or a snack food manufacturer may claim that it “buys green energy credits to match 100% of the electricity needed to produce” its snacks.⁴⁸² By purchasing such products, consumers can indirectly support renewable energy.

2. Comments

The comments discussing renewable energy focused on three issues: (1) the definition of “renewable energy” and guidance on “made with renewable energy” claims; (2) whether utilities must disclose that the renewable energy they sell is based on RECs; and (3) the types of practices and advertising claims that should be considered “double counting.”

a. Defining Renewable Energy and Interpreting Renewable Energy Claims

Several comments discussed the definition and scope of the term “renewable energy.” One recommended that the Commission clearly state what qualifies as renewable energy.⁴⁸³

⁴⁷⁹ CRS, Comment 533254-00049 at 2-3. Renewable energy is not sold in all areas of the country. However, in the U.S., more than 50 percent of consumers can purchase green power directly from their utility or electricity provider. NREL, Carbon Offsets Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/carbonoffsets/presentations/lbird.pdf>).

⁴⁸⁰ CRS, Comment 533254-00049 at 3; NREL, Carbon Offsets Workshop Tr. at 45; NREL Green Power Marketing Report at 14.

⁴⁸¹ NREL, Carbon Offsets Workshop Tr. at 48-49. Businesses also may purchase RECs to facilitate compliance with regulatory requirements. The FTC’s focus is not on these sales.

⁴⁸² See, e.g., Rob Schasel, PepsiCo, Carbon Offsets Workshop Tr. at 207.

⁴⁸³ P&G, Comment 533431-00070 at 3 (stating that an energy source is renewable if the rate of replenishment matches the rate of its consumption, the sourcing and use of the energy does not harm

⁴⁷¹ See, e.g., BPI, Green Packaging Workshop Tr. at 89; ILSR, Green Packaging Workshop Tr. at 137-138; SDA, Comment 533431-00020 at 4.

⁴⁷² 74 FR 38295, 38298 (July 31, 2009).

⁴⁷³ The USDA defines “biobased product” as a “product determined by the Secretary to be a commercial or industrial product (other than food or feed) that is (A) composed, in whole or in significant part, of biological products, including renewable domestic agricultural materials and forestry materials; or (B) an intermediate ingredient or feedstock.” *Id.*

⁴⁷⁴ See (http://www.nrel.gov/learning/re_basics.html).

⁴⁷⁵ RECs are also known as green certificates, green tags, or tradable renewable certificates. Lori Bird, National Renewable Energy Laboratory (“NREL”), Carbon Offsets Workshop Tr. at 42.

⁴⁷⁶ Although one REC generally represents the right to describe one megawatt hour of electricity as “renewable,” a REC’s precise attributes continue to be a matter of debate. NREL, Carbon Offsets Workshop Tr. at 42, 52. Moreover, no single, national standard dictates whether a REC also represents other environmental attributes that may stem from renewable energy generation, such as a reduction in air pollution. *Id.*; Ed Holt, Ed Holt & Associates (“Holt”), Carbon Offsets Workshop Tr. at 151.

⁴⁷⁷ See NREL, Carbon Offsets Workshop Tr. at 45; NREL, Carbon Offsets Workshop Presentation at (<http://www.ftc.gov/bcp/workshops/carbonoffsets/presentations/lbird.pdf>); CRS, Comment 533254-00049 at 3; Lori Bird, Claire Kreycik, and Barry Friedman, *Green Power Marketing in the United States: A Status Report*, National Renewable Energy Laboratory (Sept. 2009) (“NREL Green Power Marketing Report”), available at (<http://www.nrel.gov/docs/fy09osti/46581.pdf>) at 14.

⁴⁷⁸ Businesses and organizations purchase nearly 100 percent of these unbundled RECs. See Renewable Energy Marketers Association (“REMA”), Comment 533254-00028 at 2; NREL Green Power Marketing Report at 18.

Another asserted consumers may not have a clear understanding of the term,⁴⁸⁴ but a different commenter believed that consumers understand it to mean energy generated from sources other than fossil fuels or nuclear power.⁴⁸⁵ Another commenter stated that there is no uniform definition of “renewable energy.”⁴⁸⁶

Some commenters recommended that the Commission include guidance about the scope of renewable energy claims and the possible need to qualify them.⁴⁸⁷ One commenter provided examples of potentially broad, implied claims and suggested that the Commission include these examples in the Guides.⁴⁸⁸ For instance, consumers may interpret a “made with renewable energy” claim on a product label as applying to the product, its packaging, and the label itself.⁴⁸⁹ Several commenters also cautioned that consumers may interpret the claim “manufactured with renewable energy” to mean that the product was made entirely with renewable energy.⁴⁹⁰ In these commenters’ view, marketers should not make an unqualified “made with renewable energy” claim if less than 100 percent of the electricity used comes from renewable sources.⁴⁹¹

b. REC Disclosures

Some commenters discussed whether utilities or other electricity retailers

the ecosystem or increase the product’s environmental footprint, and the sourcing of the energy reduces consumption of non-renewable resources). Another commenter stated that a federal Executive Order defines renewable energy, and others noted that many states have different definitions of what constitutes renewable energy. Dow, Comment 533431-00010 at 13; *see also* Edison Electric Institute, Comment 533254-00055 at 4-5; Exelon Corp., Comment 533431-00059 at 5.

⁴⁸⁴ Tandus, Comment 536013-00037 at 1.

⁴⁸⁵ CRS, Comment 533254-00049 at 4.

⁴⁸⁶ Edison Electric Institute, Comment 533254-00055 at 4-5.

⁴⁸⁷ Cameron Brooks, Renewable Choice Energy (“Renewable Choice”), Carbon Offsets Workshop Tr. at 214 (encouraging the FTC to provide guidance on making more precise claims); CRS, Comment 533254-00049 at 4-14; SDA, Comment 534743-00028 at 2 (suggesting that the Commission provide guidance on which environmentally beneficial attributes are associated with the use of renewable energy, such as reductions in greenhouse gases); David A. Zonana, California Department of Justice, Carbon Offsets Workshop Tr. at 219 (stating that it generally is easier for marketers to substantiate more precise marketing claims).

⁴⁸⁸ CRS, Comment 533254-00049 at 4-14.

⁴⁸⁹ *Id.* at 10; CRS, Comment 534743-00009 at 2.

⁴⁹⁰ CRS, Comment 533254-00049 at 10; CRS, Comment 533431-00061 at 6; Jennifer Martin, CRS (“CRS”), Carbon Offsets Workshop Tr. at 194-195; Sharp Electronics Corporation, Solar Energy Solutions Group (“Sharp Electronics”), Comment 533254-00036 at 1; *see also* Dow, Comment 533431-00010 at 13 (recommending that marketers specify the percentage of renewable energy used).

⁴⁹¹ *Id.*

must disclose that the renewable energy they sell is based on their purchase of RECs.⁴⁹² Some argued that sellers should disclose this fact so consumers will not believe mistakenly that the utility either generated the renewable power itself or purchased it through electricity contracts.⁴⁹³ As one commenter explained, consumers may believe that the renewable energy they purchase is generated in their geographic location, when, in fact, the utility may have purchased RECs generated in a distant location.⁴⁹⁴ These commenters, therefore, argued that without a disclosure, consumers might be misled. The Renewable Energy Marketers Association disagreed, maintaining that a disclosure about the source of the renewable energy is unnecessary because there is no difference in the environmental benefits of REC-based renewable energy and contract-based renewable energy.⁴⁹⁵

c. Double Counting

Commenters also discussed the problem of “double counting.” Double counting generally occurs when an entity sells the same REC to more than one purchaser or when multiple parties make claims based on the same REC. Although some instances of double counting are straightforward,⁴⁹⁶ the commenters discussed more subtle variations. Some argued a company should not generate renewable power onsite (e.g., by using solar panels on store roofs), sell RECs based on the renewable attributes of that same power, and then advertise that they use renewable energy (e.g., “our stores are

⁴⁹² *See, e.g.*, Ecology Center, Comment 533254-00020 at 1; Sol Metz (“Metz”), Comment 533254-00023 at 1; REMA, Comment 533254-00028 at 3-4; James Svensson (“Svensson”), Comment 533254-00021 at 1; Weyerhaeuser, Comment 533431-00084 at 13.

⁴⁹³ Ecology Center, Comment 533254-00020 at 1; Metz, Comment 533254-00023 at 1; Svensson, Comment 533254-00021 at 1.

⁴⁹⁴ Climate Clean, Comment 533254-00039 at 3 n.7 (stating that claims such as “made with green energy” are “misleading insofar as they may imply on-site generation, not the market purchase (possibly well out of market) of environmental attributes of renewable energy production”). Another commenter stated that marketers advertise products as “produced with wind power” and questioned whether consumers understand that the wind power may be generated in a distant location. The commenter stated that many marketers include disclaimers that explain they use power from the grid. Weyerhaeuser, Comment 533431-00084 at 3.

⁴⁹⁵ REMA, Comment 533254-00028 at 3-4; *see also* CRS, Comment 533254-00049 at 2-3 (explaining that in neither case “is the consumer directly receiving actual electrons generated by the renewable energy facility, which is physically impossible”).

⁴⁹⁶ A marketer, for example, may knowingly sell the same REC multiple times.

100% solar-powered”).⁴⁹⁷ In their view, such practices constitute double counting and are misleading. Some commenters suggested, however, that it would not constitute double counting if those companies simply claimed that they “host” a renewable energy facility.⁴⁹⁸

3. Consumer Perception Evidence

No commenters submitted research exploring how consumers perceive renewable energy claims. The Commission’s study, however, explored respondents’ understanding of such claims.

The study asked respondents to describe, in their own words, what a “made with renewable energy” claim means. In response to this open-ended question, 16 percent referenced a particular form of renewable energy, such as solar or wind power. Five percent stated that the product was made with energy that is not derived from fossil fuels; four percent stated the product was made with “alternative” or “clean” energy; and one percent stated that it was made with energy that is readily replenished. Seventeen percent did not understand the claim’s meaning or stated that it meant nothing to them, and another 17 percent stated that the product was made from recycled materials.⁴⁹⁹

Through a closed-ended question, the study also explored what claims respondents thought were implied by a product advertised as “made with renewable energy.” The study provided seven possible claims from which respondents could choose. In response, 28 percent thought the claim implied the product was made with renewable materials, 21 percent thought the product was made from recycled materials, and 18 percent thought the product was recyclable.⁵⁰⁰

In addition, the study asked respondents whether a statement that a product is “made with renewable

⁴⁹⁷ Matthew Clouse, EPA Green Power Partnership (“Green Power Partnership”), Carbon Offsets Workshop Tr. at 221; CRS, Comment 533254-00049 at 6; REMA, Comment 533254-00028 at 10; Sharp Electronics, Comment 533254-00036 at 1-2.

⁴⁹⁸ CRS, Comment 533254-00049 at 6; REMA, Comment 533254-00028 at 10; Sharp Electronics, Comment 533254-00036 at 1-2.

⁴⁹⁹ In addition to these responses, 11 percent stated that the product was made with renewable energy without elaborating on what the term “renewable energy” meant. Respondents provided numerous other unique answers in response to this open-ended question. All reported findings are based on FTC staff’s more detailed analysis of responses rather than Harris’ general findings.

⁵⁰⁰ Because consumers could choose one or more claims, or no claims, the responses provided do not add up to 100 percent.

energy” suggests that all, most, or some of the product was made with renewable energy. The largest group, 36 percent, indicated that they interpret the claim as meaning that “all” of the product was made with renewable energy and 17 percent believed that “most” of it was made with renewable energy.⁵⁰¹

Finally, the study asked about a product advertisement that included the statement “our manufacturing plant hosts a solar [or wind] power facility.”⁵⁰² The study asked which, if any, of the following three claims were implied by the statement: (1) there is a solar/wind power facility on the company’s premises; (2) solar/wind power is used in making the company’s products; and (3) the company hosts a solar/wind power conference meeting in its manufacturing plants. Respondents could choose more than one answer. Eighty-five percent stated that there is a solar/wind power facility on the company’s premises, 62 percent stated that solar/wind power is used in making the company’s products, and 12 percent stated that the company hosts a solar/wind power conference meeting in its manufacturing plants.⁵⁰³

4. Analysis and Guidance

Based on the record, the Commission proposes new guidance concerning renewable energy claims.⁵⁰⁴ The following discusses this guidance and addresses the issues raised by commenters concerning consumer interpretation of renewable energy claims, REC disclosures, geographic location disclosures, and claims that could constitute “double counting.”

⁵⁰¹ Further, 23 percent stated that “some” of the product was made with renewable energy, 18 percent stated that the claim does not suggest anything about how much of the product was made with renewable energy, and seven percent stated that they were not sure. The provided figures total 101 percent because of rounding. These percentages were derived by combining the responses to all claims that included “made with renewable energy” (i.e., “made with renewable energy,” “green - made with renewable energy,” “eco-friendly - made with renewable energy,” and “sustainable - made with renewable energy”).

⁵⁰² The survey asked half of the respondents about solar power facilities and the other half about wind power facilities. Because there were no meaningful differences between the responses of these two groups, we discuss the combined results.

⁵⁰³ The results also were calculated using one response (that the company hosts a meeting in its plant) as a control claim to roughly adjust for guessing. The results net of the control are: 73 percent of respondents stated there is a solar/wind power facility on the company’s premises, and 50 percent stated that solar/wind power is used in making the company’s products.

⁵⁰⁴ This proposed guidance can be found in 16 CFR 260.14.

a. Consumer Interpretation of Renewable Energy Claims

The commenters and the Commission’s study raise three main issues related to consumer interpretation of renewable energy claims: (1) the meaning of “renewable energy”; (2) claims implied by renewable energy advertisements; and (3) potentially overbroad renewable energy claims.

First, the term “renewable energy” has an emerging meaning. Industry does not appear to have a uniform definition of the term, and commenters discussed different energy sources that they believe are “renewable.” There appears to be a consensus, however, that renewable energy excludes fossil fuels. The results of the Commission’s study suggests that a significant minority of consumers have a similar, general understanding of renewable energy; specifically, it is not derived from fossil fuels.⁵⁰⁵ Based on both this information and the comments, the Commission proposes advising marketers not to make an unqualified “made with renewable energy” claim if an item was manufactured with energy produced using fossil fuels. Given the available information, however, the Commission does not propose further guidance on which specific energy sources consumers consider to be renewable.

The second issue is the extent to which renewable energy claims require qualification. The Commission’s study suggests that some consumers believe that a “made with renewable energy” claim implies that the advertised product is also made with renewable materials (28 percent of respondents) or made from recycled materials (21 percent).⁵⁰⁶ The cause of these consumers’ confusion is not entirely apparent. Although some renewable energy is itself made from renewable or recycled materials (e.g., biomass), not all products made with renewable energy are necessarily made with such materials.

When a claim misleads a small, but significant, minority of consumers, the Commission generally advises marketers to qualify the claim to prevent deception.⁵⁰⁷ Although the Commission

⁵⁰⁵ Responding to open-ended questions, 16 percent of respondents explained the term by referring to a particular energy source (e.g., the sun, wind, biomass, and other non-fossil fuel sources), and five percent expressly stated that the energy was not derived from fossil fuels.

⁵⁰⁶ The open-ended responses are consistent with these closed-ended results.

⁵⁰⁷ For example, as discussed in the general environmental benefit claims section (Part V.A, *supra*), the Commission’s consumer perception study indicated that 27 percent of respondents

did not test any specific qualifiers, it proposes that marketers disclose the type or source of the renewable energy (e.g., solar or wind). Similar to the proposal to qualify renewable materials claims, discussed above, the Commission believes that providing context for renewable energy claims may help reduce consumers’ misperception. If consumers are armed with a better understanding of renewable energy, they may be less likely to draw inferences that are unrelated to the claim.

The Commission does not propose advising marketers to qualify renewable energy claims by specifically stating that the product does not contain renewable or recycled materials. Qualifiers such as “not made with renewable materials” or “does not contain recycled materials” bear no relation to a renewable energy claim and, therefore, could cause more consumer confusion than the qualifier alleviates. The Commission, however, requests comment on whether specifying the source of the renewable energy adequately qualifies a “made with renewable energy” claim.

Third, as with other environmental claims, marketers should be cautious that they do not overstate their renewable energy claims. For example, a vehicle manufacturer should not state that its product is made with renewable energy when the claim applies only to certain components of the vehicle. Section 260.6(b) of the Guides already advises marketers to specify whether the advertised environmental attributes apply to the product, its packaging, or only a component of the product or packaging. This guidance applies equally to renewable energy claims. The Commission proposes including new guidance about whether consumers interpret a “made with renewable energy” claim to mean the product was made entirely using renewable energy. In the Commission’s research, 36 percent of respondents interpreted a “made with renewable energy” claim to mean that “all” of the product was made with renewable energy.⁵⁰⁸ This result is consistent with several commenters’ views, as well as the Commission’s existing guidance regarding “made with recycled content” claims.⁵⁰⁹

The Commission does not have evidence, however, regarding exactly how consumers interpret the term “all”

interpreted the claims “green” and “eco-friendly” as suggesting a product has no negative environmental impact. Based in part on these findings, the Commission proposes to advise marketers to qualify general environmental benefit claims.

⁵⁰⁸ In addition, 17 percent stated that most of the product was made with renewable energy.

⁵⁰⁹ 16 CFR 260.7(e).

in this context or how broadly consumers interpret “made with renewable energy” claims. For example, for a product advertised as “made with renewable energy,” it is unclear whether consumers would expect that all product components are made with renewable energy. This ambiguity, however, does not prevent the Commission from providing some guidance. Specifically, based on its research, the commenters’ views, and its own judgment, the Commission proposes advising marketers not to use unqualified “made with renewable energy” claims unless all, or virtually all, of the significant manufacturing processes used to make the product are powered by renewable energy or powered by conventionally produced energy that is offset by RECs.⁵¹⁰ For example, it would be deceptive for a toy manufacturer to make an unqualified renewable energy claim if it did not purchase renewable energy to power all of the significant processes used to manufacture its toys. Determining whether that same manufacturer could make an unqualified claim if its plant were powered with renewable energy, but its delivery trucks used fossil fuels, would require further consumer perception research. The Commission requests comment on this proposed advice and seeks any additional consumer perception evidence addressing this issue.

b. REC Disclosures

The Commission also considered whether specific disclosures are necessary for renewable energy claims based on the purchase of RECs, rather than the purchase through contracts. As discussed earlier, the commenters held different opinions on this issue. Some argued that sellers must inform consumers when their renewable energy sales are based on RECs because consumers would otherwise assume that the marketer either generated the renewable energy itself or purchased it through contracts. The commenters, however, did not submit consumer perception evidence to support this view.

Even assuming that consumers thought renewable energy claims were based on contractual purchases (rather than REC purchases), there is no reason to believe that this fact would be material to consumers. No evidence on the record suggests that a contract-based system more reliably tracks renewable

energy than a well-designed REC-based system. Accordingly, the Commission does not have a sufficient basis to advise marketers to disclose that their renewable energy claims are based on RECs.

c. Geographic Location of Renewable Energy Generation

Regardless of whether the marketer purchases renewable energy through RECs or contracts, the energy may have been generated in a distant geographic location. It is unclear whether consumers interpret renewable energy claims to mean that the energy was generated in their location and, thus, yields local benefits. As discussed above, marketers must have substantiation for all reasonably implied interpretations of their claims. Therefore, marketers must evaluate the net impression of their advertisements and, when needed, obtain consumer research to determine if their advertisements imply that the renewable energy was generated locally. If a particular advertisement implies that renewable energy yields local benefits, marketers should inform consumers that this is not the case to prevent deception. Because the need for such disclosures will depend on the specific advertisement in question, the Commission does not propose adding guidance on this issue to the Guides. Nevertheless, marketers should be mindful of this issue to avoid misleading consumers.

d. Double Counting

Double counting can occur as a result of fraud or inadequate accounting, as well as in more subtle ways.⁵¹¹ Fraudulent activity, such as knowingly selling the same offset to multiple purchasers, is best addressed through law enforcement actions rather than Commission guidance. The Commission’s Guides are intended for those marketers seeking to comply with the law.

Aside from outright fraud, the written comments provide examples of more

⁵¹¹ CRS, Comment 533254-00049 at 5-6; *see also* Holt, Carbon Offsets Workshop Tr. at 153; NREL, Carbon Offsets Workshop Tr. at 51. Because REC sales often involve multiple transactions and a large number of entities, businesses must track RECs through the market. Therefore, inadequate accounting or tracking practices can lead marketers to sell multiple certificates based on the same renewable energy activity. Accurate, well-designed registries or tracking systems can help to minimize this problem. For example, several regional tracking systems, covering more than 30 states, use metered generation data for the issuance of RECs. CRS, Comment 533254-00049 at 3 n.3; REMA, Comment 533254-00028 at 4-5; *see also* Holt, Carbon Offsets Workshop Tr. at 153; NREL, Carbon Offsets Workshop Tr. at 51.

subtle methods of double counting. Guidance for these types of practices may be useful. The Commission agrees with commenters that companies should not sell RECs for renewable energy they generate onsite (*e.g.*, by using solar panels on store roofs) and then tout their renewable energy facilities or equipment in advertising (*e.g.*, “this store is 100% solar powered”). By selling RECs, the company has transferred the right to characterize its electricity as renewable. Therefore, even if the company technically uses the electricity from its onsite solar panels, an advertising claim about the renewable aspects of this energy is misleading. The Commission, therefore, proposes to include this example in the Guides.

Some commenters suggested companies in these circumstances should be able to claim that they “host a renewable energy facility.” The Commission’s study, therefore, tested this claim, and 62 percent of respondents stated that the company used solar/wind power to make its products.⁵¹² The Commission, therefore, proposes advising marketers that the phrase “hosts a renewable energy facility” is likely to mislead consumers if, in fact, the company has sold its rights to claim credit for the renewable energy.

E. Carbon Offset Claims

Carbon offsets, relatively new products in the green marketing field, received significant attention in the comments. To provide background on the consumer protection issues involved with these products, the following describes offsets and the advertising claims associated with them. It then discusses the comments addressing this topic, relevant consumer perception research, and the Commission’s analysis of the issues.

1. Overview

Carbon offsets are credits or certificates that represent reductions in greenhouse gas (“GHG”) emissions. These reductions stem from different types of projects, such as methane capture from landfills or livestock feedlots, tree planting, and industrial gas destruction.⁵¹³ Marketers quantify

⁵¹² As discussed in note 503, using a control claim yields similar results. Net of control, 50 percent of respondents believe the company used solar/wind power to make its products.

⁵¹³ These projects occur around the globe, often in locations removed from offset purchasers. The location of an offset project is immaterial to its impact on greenhouse gas levels because these gases circulate evenly throughout the earth’s atmosphere. Katherine Hamilton, Ecosystem Marketplace (“Ecosystem”), Carbon Offsets Workshop Tr. at 31.

⁵¹⁰ The Commission also applies the “all or virtually all” standard to unqualified “Made in USA” claims. *See* Enforcement Policy Statement on U.S. Origin Claims, 62 FR 63760, 63755 (Dec. 2, 1997).

their GHG reductions and then sell carbon offsets to purchasers seeking to meet their own environmental goals by reducing their “carbon footprints” or by striving to make themselves “carbon neutral.”⁵¹⁴ Offset purchasers include individual consumers, businesses, government agencies, and non-profit organizations.⁵¹⁵

Individual consumers, for example, generally purchase offsets to reduce, balance, or neutralize greenhouse gas emissions associated with their own activities, such as automobile use or airplane travel. In these instances, offset sellers advertise their products directly to individual consumers. For example, some online travel vendors have partnered with offset sellers to allow consumers to buy offsets when they purchase airplane tickets.⁵¹⁶

Businesses purchase carbon offsets to balance the emissions associated with the production, sale, or use of their own products and services. They often tout these offsets in advertisements for their products and services. For example, a potato chip seller that purchases offsets to match its GHG emissions might advertise its chips as “carbon neutral.” Marketers make similar claims for a wide range of products and services, from clothing to paper goods.⁵¹⁷

⁵¹⁴ No uniform definition for either term appears to exist. See, e.g., Exelon Corp., Comment 533431-00059 at 4 (stating that there is no clear consensus as to what the term “carbon footprint” includes); *Carbon Claims and the Trade Practices Act*, Australian Competition & Consumer Commission (June 2008) at 7, available at (<http://www.accc.gov.au/content/index.phtml/itemId/833279>) (discussing “carbon neutrality”). “Carbon footprint” generally refers to the net greenhouse gas emissions caused by the activities of an individual, business, or organization. “Carbon neutral” generally describes an entity whose greenhouse gas emissions net to zero.

⁵¹⁵ Ecosystem, Carbon Offsets Workshop Tr. at 37-38 and (<http://www.ftc.gov/bcp/workshops/carbonoffsets/presentations/khamilton.pdf>). The vast majority (80 percent) of offset purchasers in the international voluntary market are businesses. Across the globe, offset sales generally occur in two types of markets: (1) those that facilitate compliance with regulatory targets (so-called “mandatory” or “compliance” markets); and (2) those unrelated to existing regulatory programs (so-called “voluntary” markets). This discussion addresses offsets in the voluntary market.

⁵¹⁶ Matthew Kotchen, University of California, Santa Barbara, Carbon Offsets Workshop Tr. at 92.

⁵¹⁷ See generally EcoSecurities, Comment 533254-00044 at 4-5. Although many businesses purchase offsets to make advertising claims for individual products, others do so to prepare for future mandatory carbon markets, to help their corporate image more generally, or to promote corporate responsibility efforts. See, e.g., Ecosystem, Carbon Offsets Workshop Tr. at 40-41; Mario Teisl, University of Maine, Carbon Offsets Workshop Tr. at 175. The Commission has not identified any data addressing the volume of purchases attributable to these various activities.

2. Comments

a. Defining Carbon Offsets and Requiring Disclosures

The comments differed in the degree and extent the FTC should be involved in regulating carbon offset marketing. Several commenters called on the Commission to provide detailed guidance or create a regulatory framework for offsets.⁵¹⁸ For example, some suggested that the FTC define or clarify the meaning of certain terms, such as “carbon neutral.”⁵¹⁹ Another asked the FTC to establish a list of allowable offset projects and mandate uniform calculation methods for emission reductions.⁵²⁰ Others urged mandatory disclosures about the type of activity (e.g., reforestation) that forms the basis for carbon offsets.⁵²¹ In addition, Consumers Union called for an annual FTC statement about the amount of global carbon production to help consumers compare the offset impacts in a global context.⁵²²

While some commenters called for regulatory requirements, others urged the FTC to avoid setting standards.⁵²³ For example, Exelon Corporation stated that the FTC lacks the technical expertise and authority to set standards in this area.⁵²⁴ Walmart indicated that,

⁵¹⁸ See Climate Clean, Comment 533254-00039 at 5; Consumers Union, Comment 533254-00026 at 1-2; NativeEnergy, Inc., Comment 533431-00044 at 2; State of New Jersey, Department of Environmental Protection (“NJ DEP”), Comment 533431-00082 at 1; Pacific Gas & Electric Company, Comment 533254-00041 at 1; Seventh Generation, Comment 533431-00033 at 6.

⁵¹⁹ See, e.g., Urvashi Rangan, Consumers Union (“Consumers Union”), Carbon Offsets Workshop Tr. at 210 (“I think clarification of terminology out there is really important. Things like carbon-free, carbon neutral, carbon offset, carbon negative . . . are really confusing to consumers.”); International Paper, Comment 533431-00006 at 2; Kim Sheehan, Comment 533431-00004 at 1.

⁵²⁰ NJ DEP, Comment 533431-00082 at 2.

⁵²¹ Consumers Union, Comment 533254-00026 at 2 (recommending disclosure of offset type); Hydrodec North America LLC (“Hydrodec”), Comment 533254-00046 at 8 (same); NJ DEP, Comment 533431-00082 at 2 (recommending disclosure of the name, owner, and location of the project that produced the emission reductions, among other things); 3M Company, Comment 533431-00027 at 2 (recommending disclosure of the source of and methodology used to calculate the carbon offsets); see also Carbon Offset Providers Coalition (“COPC”), Comment 533254-00032 at 4 (recommending that the FTC promote “clarity and transparency”).

⁵²² Consumers Union, Comment 533254-00026 at 1-2. Consumers Union also recommended that sellers disclose the benefits that the product yields beyond the baseline impacts (*i.e.*, the emissions that would have occurred in the absence of the offset project).

⁵²³ See, e.g., Constellation Energy Group, Inc. (“Constellation”), Comment 533254-00029 at 4-5; Hydrodec, Comment 533254-00046 at 5; Wal-Mart Stores, Inc. (“Wal-Mart”), Comment 533254-00040 at 3-4.

⁵²⁴ Exelon Corp., Comment 533431-00059 at 2.

while the FTC should insist that marketers have a reasonable basis for their claims, the agency should not mandate one reasonable approach over another.⁵²⁵ In addition, Constellation Energy Group noted that, given the relative youth of these products, “market-driven solutions are being and will continue to be developed to address consumer confidence or credibility concerns.”⁵²⁶ Finally, commenters warned that any FTC action in this area might negatively impact ongoing policy debates at the federal and state levels.⁵²⁷

b. Timing of Emission Reductions

The comments also raised concerns about the timing of the actual GHG emission reductions associated with carbon offsets. Some reductions occur prior to the sale of offsets and others occur after. For example, offsets generated from methane capture activities are typically sold after the methane reductions occur. Other sellers, however, use offset proceeds to fund future projects (such as constructing renewable energy facilities) that are expected to create emission reductions at a later date.

Many commenters stated that offsets should be based on prior emission reductions because those reductions are verifiable.⁵²⁸ The commenters disagreed, however, about the propriety of selling offsets based on future GHG reductions. One commenter preferred such offsets because, in its view, consumers are concerned with future GHG emissions.⁵²⁹ Another suggested that consumers implicitly understand that reductions from activities such as tree-planting do not happen immediately but rather “incrementally and over a longer time horizon.”⁵³⁰ Others disagreed and argued that consumers do not necessarily understand that emission reductions funded by their purchase have not yet

⁵²⁵ Wal-Mart, Comment 533254-00040 at 3-4.

⁵²⁶ Constellation, Comment 533254-00029 at 2.

⁵²⁷ See Exelon Corp., Comment 533431-00059 at 2; Wal-Mart, Comment 533254-00040 at 3-4.

⁵²⁸ See, e.g., Edison Electric Institute, Comment 533254-00055 at 10; Michael Gillenwater (“Gillenwater”), Comment 533254-00005 at 3; The Fertilizer Institute, Comment 533254-00052 at 4. One commenter, however, noted that such sellers cannot show that the offset purchase *caused* an emission reduction. NativeEnergy, Inc., Comment 533431-00044 at 3 (“As one cannot change the past, it is impossible for the purchase of a previously generated reduction to be the cause of that reduction.”)

⁵²⁹ NativeEnergy, Inc., Comment 533431-00044 at 3.

⁵³⁰ Edison Electric Institute, Comment 533254-00055 at 17 (stating that as long as the offset is substantiated, timing should not be an issue).

occurred.⁵³¹ In one commenter's view, sellers should disclose prominently that the reductions caused by their products will occur in the future.⁵³²

In addition to concerns about consumer understanding, many commenters raised concerns about the certainty of future projects.⁵³³ With forestry-based offsets, for instance, events such as fire or insect infestation may damage trees and release carbon stored within them.⁵³⁴ Because of these uncertainties, one commenter stated that offsets for unverified emission reductions should not be allowed.⁵³⁵ Others suggested that offset sellers take steps to account for such uncertainties, such as using accounting practices to reflect the risks associated with future projects.⁵³⁶

c. Substantiating Carbon Offset Claims – Additionality

One of the most contentious issues surrounding the substantiation of carbon offset claims is the concept of “additionality,” specifically, whether reductions associated with a carbon offset product would have occurred without the offset sale.⁵³⁷ Both the workshop participants and comments discussed this issue at length, with most agreeing that offset sellers have a duty to demonstrate that their underlying GHG reduction projects are additional.⁵³⁸ Without such a showing,

the underlying projects do not produce meaningful GHG reductions.⁵³⁹

The concept of additionality raises difficult technical and policy challenges, which have generated substantial disagreement among experts. In particular, the commenters did not form a consensus regarding which tests industry members should use to determine whether an offset project is additional. In fact, according to various commenters, industry members rely on numerous, different tests, alone or in combination. Examples of these various tests include:⁵⁴⁰

- **Regulatory/Legal Test:** Addresses whether the project, and, thus, the emissions reductions, are required by law. If they are required by law, the project is not additional.

- **Investment Test:** Addresses whether the revenue from carbon offset sales was a decisive factor in the project's implementation or whether the project would have yielded a lower than acceptable rate of return without offset revenue. If either is true, the project is additional.

- **Common Practice Test:** Addresses whether the project involves widely-used technologies and is merely a “business as usual” project. If so, the project is not additional.

- **Technology Test:** Addresses whether the project involves a technology that is not considered “business as usual” or whether the primary benefit yielded by the technology is a reduction in emissions. If so, the project is additional.

- **Timing Test:** Addresses whether the project began after a specific date. This test eliminates older projects which could not have been implemented with the intent of reducing emissions. If the project began after the established date, it is additional.

- **Barriers Test:** Addresses whether there are barriers, such as local opposition or lack of knowledge, that

must be overcome to implement the project. If the project succeeds in overcoming unusual barriers such as these, the project is additional.

- **Performance Test:** Addresses whether the project achieves a level of performance (e.g., an emission rate, a technology standard, or a practice standard) with respect to emission reductions and/or removals that is significantly better than “business as usual.” If so, the project is additional.⁵⁴¹

The commenters variously criticized these tests as vague, subjective, and likely to yield undesirable outcomes. For example, one commenter noted that the investment test requires “subjective analyses of the intent of the project developer or the sufficiency of a project's investment return . . . [and ignores] market realities as they relate to capital formation and the tenure of commercial arrangements which make private activity projects feasible.”⁵⁴² Such subjective criteria encourage “gaming” and usually result in increased costs.⁵⁴³ Another criticized the common practice, technology, and barrier tests because they all involve “complex counter-factual questions of what constitutes the baseline scenario . . . and how the offset project differs.”⁵⁴⁴ Still another noted that the timing test may create incentives to delay much-needed investments until an offset system is established.⁵⁴⁵ Some workshop participants, however, supported the regulatory additionality test because it offers an objective standard (i.e., if the law requires the project, one cannot sell offsets from it).⁵⁴⁶ But even this approach drew criticism when one panelist explained that multiple regulations can apply to a project, making it difficult to determine whether regulations actually require a particular technology investment.⁵⁴⁷

⁵³¹ See, e.g., AgRefresh, Comment 533254-00004 at 1, 6; TerraPass, Inc. (“TerraPass”), Comment 533254-00045 at 5.

⁵³² AgRefresh, Comment 533254-00004 at 1, 6.

⁵³³ Climate Clean, Comment 533254-00039 at 5; see Wiley Barbour, Environmental Resources Trust, Inc. (“ERT”), Carbon Offsets Workshop Tr. at 216 (“There are real differences of opinion about whether or not a forestry project, which is going to take fifty years to grow, . . . should be counted as a reduction today.”).

⁵³⁴ Offset Quality Initiative, Comment 533254-00047 at 8.

⁵³⁵ AgRefresh, Comment 533254-00004 at 6.

⁵³⁶ For example, one commenter stated that “[s]elling emission offsets before they are created is not inherently problematic However, forward crediting should be done transparently and provisions made for failure of delivery.” Gillenwater, Comment 533254-00005 at 3.

⁵³⁷ Some commenters noted that it is difficult to define additionality, and FTC staff have set forth merely one variation (examining whether the emission reduction project would have gone forward without the additional revenue stream associated with the sale of carbon offsets). Another variation examines whether the project causes emissions beyond what is required by law or beyond “business as usual.” See, e.g., Anadarko Petroleum Corp. (“Anadarko”), Comment 533254-00058 at 4. The Commission discusses these differences in more detail below.

⁵³⁸ See, e.g., Anadarko, Comment 533254-00058 at 3; Derik Broekhoff, World Resources Institute (“WRI”), Carbon Offsets Workshop Tr. at 123-125, 165; COPC, Comment 533254-00032 at 5; CRS, Comment 533254-00049 at 11; EcoSecurities, Comment 533254-00044 at 4; Gillenwater, Comment 533254-00005 at 3; Hydrodec, Comment

533254-00046 at 6; Offset Quality Initiative, Comment 533254-00047 at 4; TerraPass, Comment 533254-00045 at 5.

⁵³⁹ See, e.g., TerraPass, Comment 533254-00045 at 5.

⁵⁴⁰ See Anadarko, Comment 533254-00058 at 4; EcoSecurities, Comment 533254-00044 at 9; Gillenwater, Comment 533254-00006 at 8; Green Power Partnership, Carbon Offsets Workshop Tr. at 241-242; Holt, Carbon Offsets Workshop Tr. at 154-155; Hydrodec, Comment 533254-00046 at 4-5; Maurice LeFranc, EPA (“LeFranc EPA”), Carbon Offsets Workshop Tr. at 143; Offset Quality Initiative, Comment 533254-00047 at 4-8; WRI, Carbon Offsets Workshop Tr. at 123-125; Mark Trexler, Derik Broekhoff, and Laura Kosloff, *A Statistically-Driven Approach to Offset-Based GHG Additionality Determinations: What Can We Learn?*, Sustainable Development Law and Policy (Winter 2006) at 30, available at (<http://conserveonline.org/workspaces/climate.change/carbonmarkets/AdditionalityOffset>).

⁵⁴¹ The EPA Climate Leaders program recommends this approach for use in evaluating offsets by its partners. See (<http://www.epa.gov/stateply/>); LeFranc EPA, Carbon Offsets Workshop Tr. at 143.

⁵⁴² COPC, Comment 533254-00032 at 3. Another commenter explained that the investment test is subjective because there are no industry-specific metrics on whether an internal rate of return is “attractive” or not to project developers.” Anadarko, Comment 533254-00058 at 6.

⁵⁴³ COPC, Comment 533254-00032 at 3. A workshop participant also noted that it may be difficult to determine which source of funding “made a difference.” Green Power Partnership, Carbon Offsets Workshop Tr. at 242.

⁵⁴⁴ Anadarko, Comment 533254-00058 at 6.

⁵⁴⁵ Hydrodec, Comment 533254-00046 at 5.

⁵⁴⁶ Anadarko, Comment 533431-00032 at 4; Renewable Choice, Carbon Offsets Workshop Tr. at 262; see also LeFranc EPA, Carbon Offsets Workshop Tr. at 143.

⁵⁴⁷ ERT, Carbon Offsets Workshop Tr. at 254-256; see also Anja Kollmus, Stockholm Environmental

Many commenters urged the FTC to refrain from issuing guidelines that address additionality. They suggested that a combination of legislative action, efforts by agencies with greater expertise, and evolving market practices are the best means for addressing these questions.⁵⁴⁸ For example, one commenter warned that the “FTC risks becoming entangled in highly complex policy issues at the core of ongoing discussions concerning the design of market-based mechanisms addressing climate change.”⁵⁴⁹ Another argued that, because pending legislation would assign the role of addressing additionality standards to agencies other than the FTC, it would be neither “appropriate nor productive for the FTC to take a stance on the issue” at this time.⁵⁵⁰

d. Substantiating Carbon Offset Claims – Use of RECs

Some carbon offsets are based on the purchase of renewable energy certificates (“RECs”). The practice of using RECs to create carbon offsets is controversial and garnered significant attention at the workshop and in the comments.⁵⁵¹

Some workshop panelists and commenters approved of using RECs to substantiate offset claims.⁵⁵² In their view, renewable energy generation (represented by RECs) creates emission reductions by causing fossil fuel-fired facilities to produce less energy and, therefore, fewer emissions.⁵⁵³

Institute (“SEI”), Carbon Offsets Workshop Tr. at 258-259.

⁵⁴⁸ AF&PA, Comment 533254-00042 at 2-3; Anadarko, Comment 533254-00058 at 2; Clean Air Conservancy, Comment 533254-00027 at 1; COPC, Comment 533254-00032 at 3; Edison Electric Institute, Comment 533254-00055 at 11-13; Exelon Corp., Comment 533431-00059 at 2-3; Hydrodec, Comment 533254-00046 at 5-6; REMA, Comment 533254-00028 at 12; The Fertilizer Institute, Comment 533254-00052 at 5; Weyerhaeuser, Comment 533431-00084 at 2.

⁵⁴⁹ Anadarko, Comment 533254-00058 at 2.

⁵⁵⁰ Hydrodec, Comment 533254-00046 at 6.

⁵⁵¹ Carbon Offsets Workshop participant Edward Holt provided an overview of the issues involved in using RECs to form the basis for carbon offset claims. Holt, Carbon Offsets Workshop Tr. at 150-158.

⁵⁵² Adam Stern, TerraPass (“TerraPass”), Carbon Offsets Workshop Tr. at 227-228 (stating that there are reputable organizations such as “the World Resources Institute, The Union of Concerned Scientists, Natural Resources Defense Council, that have all indicated a support for using RECs as an offset value”); Eric Carlson, Carbonfund.org, Carbon Offsets Workshop Tr. at 229-230; CRS, Comment 533254-00049 at 9; Edison Electric Institute, Comment 533254-00055 at 6.

⁵⁵³ Carbonfund.org, Carbon Offsets Workshop Tr. at 229-230; CRS, Comment 533254-00049 at 4; Edison Electric Institute, Comment 533254-00055 at 6. One commenter argued that it “is universally accepted that the generation of renewable energy can displace and reduce the emission of carbon and

Others argued that RECs should not be used for offsets because the two are distinctive commodities and conflating them could mislead consumers.⁵⁵⁴ They provided three main arguments to support their position. First, they argued that there is little or no evidence that renewable energy generation always reduces traditional power generation⁵⁵⁵ because the actual emission reductions associated with grid power vary considerably across the United States, and there are no uniform standards for calculating the emissions displaced by renewable energy.⁵⁵⁶ Second, even if such displacement occurs, sellers cannot prove that renewable energy generation, and any associated GHG emission reductions, are additional.⁵⁵⁷ Some argued that RECs merely subsidize existing projects and do not contribute sufficiently to a project’s income stream to create a market for new renewable energy generation.⁵⁵⁸ Third, the critics questioned whether the renewable energy generators can take credit for the emission reductions that occur at fossil fuel-fired facilities.⁵⁵⁹ There is currently no mechanism to establish who owns such emission reductions – the renewable energy generator or the fossil fuel-fired

other greenhouse gases” from conventional facilities. The commenter further stated that the practice is recognized by international offset programs including the United Nations’ Clean Development Mechanism of the Kyoto Protocol, the Gold Standard, and the Voluntary Carbon Standard. CRS, Comment 533254-00049 at 11. Some of these commenters, however, cautioned that RECs do not always equate to reduced emissions from conventional facilities, and offset sellers must demonstrate that the reduced emissions are additional. COPC, Comment 533254-00032 at 2-3; CRS, Comment 533254-00049 at 3-7; Offset Quality Initiative, Comment 533254-00047 at 11.

⁵⁵⁴ Climate Clean, Comments 533254-00038 at 1-3, 533254-00039 at 3 (stating that use of RECs as offsets is a “uniquely American practice”); Gillenwater, Comment 533254-00006 at 15-16; 533254-00007 at 5 (stating that there is an incentive to rely on RECs as a source of offsets because RECs are generally less expensive than most offset projects); SEI, Carbon Offsets Workshop Tr. at 226-227.

⁵⁵⁵ Gillenwater, Comment 533254-00006 at 16 (stating that “the effect of an input of electricity from a renewable generator on other grid-connected generators [e.g., fossil fuel plants] is difficult to quantify”); EcoSecurities, Comment 533254-00044 at 3-4.

⁵⁵⁶ *Id.*

⁵⁵⁷ EcoSecurities, Comment 533254-00044 at 4 (stating that RECs “are subject to no . . . additionality testing requirements, and require no reference to whether or not the REC market was instrumental in the development of the project”); Climate Clean, Comments 533254-00038 at 2, 533254-00039 at 2-3; *see also* NREL, Carbon Offsets Workshop Tr. at 75-76 (explaining the concept of additionality for RECs).

⁵⁵⁸ *Id.*

⁵⁵⁹ ERT, Carbon Offsets Workshop Tr. at 225 (“[W]hat you’re saying is [that] you own a reduction on someone else’s property.”); *see also* Gillenwater, Comment 533254-00006 at 14.

generator.⁵⁶⁰ Therefore, the comments raised concerns about double counting if both generators take credit for the same emission reduction.⁵⁶¹

3. Consumer Perception Evidence

Some commenters emphasized the need to research consumer understanding of specific terms and claims in carbon offset advertisements.⁵⁶² The commenters, however, did not identify existing consumer perception data in this area.⁵⁶³ Therefore, the Commission tested certain issues related to carbon offset claims in its consumer research. The study split respondents into two groups – asking one about carbon offsets and the other about carbon neutrality. The research explored respondents’ understanding of these terms, whether respondents had seen advertisements for carbon offsets or for products or services described as carbon neutral, and whether they had ever purchased such items.

A significant percentage of respondents demonstrated a general understanding of carbon offsets when they chose from a list of possible descriptions, but a much smaller percentage could describe a carbon offset in their own words. Specifically, in response to a closed-ended question, 41 percent identified a carbon offset as “a way of reducing carbon dioxide and other greenhouse gases,” while 35 percent stated that they were not sure

⁵⁶⁰ Holt, Carbon Offsets Workshop Tr. at 151-152. In contrast, other emission reduction projects have a clear owner who can take credit for the reductions or sell the reductions.

⁵⁶¹ EcoSecurities, Comment 533254-00044 at 10. For example, a renewable energy generator might claim that its RECs represent a reduction in traditional electricity generation and a corresponding reduction in emissions. However, these reductions actually occur at the fossil fuel plant. The fossil fuel plant could argue that, because it produced less energy, it caused the reduction in emissions. The fossil fuel plant could sell offsets that represent the same emission reduction as the RECs.

⁵⁶² Vermont Office of Attorney General (“Vermont AG”), Comment 553254-00051 at 5 (writing on behalf of the Offices of the Attorneys General of Arkansas, California, Connecticut, Delaware, Illinois, Maine, Mississippi, New Hampshire, Oklahoma, and Vermont).

⁵⁶³ *See* Georgia-Pacific, Comment 553254-00059 at 2 (“We do not know of specific, credible surveys or even market sensing studies on this matter.”); Rebecca Tushnet, Georgetown University Law Center, Carbon Offsets Workshop Tr. at 82-83 (stating that companies’ consumer research is likely to be part of a marketing initiative and, therefore, proprietary). In considering potential consumer research, some noted that consumer interpretation of claims may change over time. *Id.*; Alan Levy, FDA, Carbon Offsets Workshop Tr. at 80; GE AES Greenhouse Gas Services LLC, Comment 533254-00043 at 2.

what a carbon offset was.⁵⁶⁴ When asked to describe a carbon offset in their own words, only 18 percent provided an answer which communicated a general understanding of the term, while 58 percent stated that they did not know or provided no response to the question.⁵⁶⁵ A much smaller number (11 percent) reported seeing an advertisement for an offset and only two percent actually recalled purchasing a carbon offset.⁵⁶⁶

In a closed-ended question, the study also asked respondents to identify what it meant to be “carbon neutral.” Thirty-nine percent of respondents answered that greenhouse gases, such as carbon dioxide, were offset. Twenty-five percent were not sure what “carbon neutral” meant.⁵⁶⁷ When asked to describe the term in their own words, 22 percent provided an answer that demonstrated a general understanding of the term, and 35 percent stated that they did not know or provided no answer.⁵⁶⁸ Similar to the carbon offset results, few respondents (only 10 percent) recalled seeing an advertisement for carbon neutral products or services, and only four percent stated that they had purchased a product or service at least partly because it was advertised or labeled carbon neutral.

For the subset of respondents who generally understood that carbon offsets were a way to reduce greenhouse gas emissions, the study attempted to gauge their understanding about the timing of

greenhouse gas emission reductions.⁵⁶⁹ The study asked each respondent to consider an airline advertisement that states: “For every flight you take with us, we will buy carbon offsets to offset the greenhouse gas emissions from your flight.” The study explained that the offsets in question involve capturing and destroying methane. It then described two methane projects that both result in reduced emissions, but in different timeframes. The study attempted to gauge respondents’ views on whether the timing of the emission reductions was material. For each project, the study asked whether respondents agreed or disagreed with the airline’s statement that it offsets the emissions from their flight. When the methane was to be captured “within the next few months,” 53 percent of respondents agreed that the airline was offsetting emissions from the flight and 20 percent disagreed.⁵⁷⁰ But when the equipment used to capture methane had not yet been installed and the methane was not to be captured “for several years,” only 28 percent of respondents agreed that the airline was offsetting emissions from the flight, while 43 percent disagreed.⁵⁷¹

4. Analysis and Guidance

The Commission proposes to provide only limited guidance regarding carbon offsets in the Guides.⁵⁷² Although many commenters urged the Commission to provide detailed advice or extensive regulatory requirements, such an approach is not appropriate at this time given the extent of the Commission’s authority, the available consumer perception evidence, and the ongoing policy debates among experts in the field concerning the appropriate tests to substantiate offset claims. However, it is appropriate for the Commission to provide advice to marketers regarding some aspects of carbon offset marketing and we discuss these below. Regardless of the Guides’ scope, the Commission may take law enforcement action to stop deceptive practices involving carbon offset marketing pursuant to Section 5 of

the FTC Act. For example, clearly deceptive activity, such as knowingly selling the same offset to multiple purchasers, does not need to be addressed in the Guides and, indeed, is best addressed through enforcement actions.

a. Consumer Interpretation of Claims and Disclosures

Some commenters asked the Commission to define terms such as carbon offsets and require sellers to disclose to consumers certain characteristics of their offsets. As previously discussed, under the FTC Act, the Commission has authority to combat deceptive and unfair practices. It does not have authority to develop environmental policies or regulations. Accordingly, the Commission does not create definitions or standards for environmental terms. Rather, it provides guidance to marketers on how consumers understand those terms. The Commission’s study suggests that some consumers have a general understanding of carbon offsets and products advertised as carbon neutral, but few reported seeing advertisements for such items, and even fewer have actually purchased them. The study did not identify any pattern of confusion among respondents about what a carbon offset is that would warrant any general FTC guidance. The Commission, therefore, does not believe a discussion about consumer understanding of these terms in the Guides would be useful to marketers. In addition, any such guidance could become obsolete quickly given this rapidly evolving market.

Marketers also requested more detailed FTC guidance with respect to the identification of allowable offset projects and the establishment of uniform methodologies for calculating emission reductions. Such guidance, however, would place the Commission in the role of setting environmental policy, which is outside the agency’s authority. The Commission, therefore, declines to do so.

Except as described below, the Commission does not propose advising offset sellers to make certain disclosures, such as the type of projects funded by the offset sales. Although such disclosures may provide helpful information to potential purchasers, there is no evidence on the record to conclude that they are necessary to prevent consumer deception. This distinction is critical under FTC law. Pursuant to the FTC Act, advertisers must disclose information that is necessary to prevent consumers from being misled – not all information that

⁵⁶⁴ The other responses were: a way of eliminating all pollution that results from using a product or service; a method for replacing scarce carbon resources; a way of reducing chemical pollutants in water; a way of making carbonated beverages; a laundry additive for removing pencil and ink stains from clothing; and none of the above.

⁵⁶⁵ These figures are based on FTC staff’s more detailed analysis of responses rather than Harris’ general findings. Examples of responses that indicate an understanding of the term include: “A way to reduce greenhouse gases”; “Trees are planted or other environmental restoration is performed to supposedly make up for environmental damage being caused by other activities”; and “A credit on the amount of carbon used in manufacturing process.”

⁵⁶⁶ Of those few who purchased an offset, 21 percent stated that they were offsetting airline travel, 15 percent automobile travel, and 15 percent lighting.

⁵⁶⁷ The other responses were: no pollution was generated in making the product; carbon resources were not used in making the product; water pollutants were reduced to improve water quality; clothing that resists pencil and ink stains; soft drinks that were made without carbonation; and none of the above.

⁵⁶⁸ These findings are based on FTC staff’s more detailed analysis of responses rather than Harris’ general findings. Examples of responses that indicate an understanding of the term “carbon neutral” include: “The amount of carbon created in producing the product is offset by other means that eliminates carbon”; “doesn’t have a negative impact in terms of carbon emissions”; and “does not leave a carbon footprint.”

⁵⁶⁹ As mentioned above, the study asked approximately half of all respondents about carbon offsets (and the remainder about carbon neutral claims). Of the 1,879 respondents who answered carbon offset questions, 770 generally understood carbon offsets. Only these 770 respondents answered questions about the timing of emission reductions.

⁵⁷⁰ Additionally, 16 percent stated that they neither agreed or disagreed and 11 percent stated that they were not sure.

⁵⁷¹ Additionally, 16 percent stated that they neither agreed or disagreed and 12 percent stated they were not sure. These figures add up to 99 percent because of rounding.

⁵⁷² This proposed guidance can be found in 16 CFR 260.5.

consumers may deem useful.⁵⁷³ Therefore, the Commission declines to advise marketers to provide such information in every offset advertisement.⁵⁷⁴

b. Timing of Emission Reductions

Some commenters suggested that the Commission advise marketers to disclose the fact that their offsets reflect emission reductions scheduled to occur in the future. The Commission's study, therefore, explored respondents' views on the timing of emission reductions. The results suggest that this timing is important to consumers.⁵⁷⁵ Specifically, when emission reductions did not occur for several years, 43 percent of respondents indicated that the carbon offset claim was misleading.⁵⁷⁶ Accordingly, marketers may need to qualify their offset claims to avoid deceiving consumers. Absent evidence that consumers view their claims differently, the Commission proposes advising marketers to disclose if the offset purchase funds emission reductions that will not occur for two years or longer.⁵⁷⁷ The Commission, however, requests comment on this proposed disclosure.

c. Substantiating Carbon Offset Claims – Tracking Offsets

Like all marketers, carbon offset marketers must ensure that their advertising claims are truthful, not misleading, and substantiated. Section 260.2 of the proposed, revised Guides explains that substantiation for environmental marketing claims often requires competent and reliable scientific evidence. Carbon offset sellers – particularly those new to the market – must pay special attention to this substantiation requirement given the complexities of substantiating offsets. For example, marketers must employ sophisticated accounting protocols to properly quantify the GHG emission reductions that result from a project, as

⁵⁷³ FTC Deception Policy Statement, 103 F.T.C. at 165.

⁵⁷⁴ In some contexts, sellers may nevertheless wish to disclose this information to differentiate their offsets.

⁵⁷⁵ As discussed above, this finding is based on the subset of respondents who generally understood carbon offsets. Despite the smaller sample size, the Commission relies on these findings because they provide the only available consumer perception evidence upon which to base guidance.

⁵⁷⁶ The study asked respondents about an airline's statement that it would buy carbon offsets to offset the greenhouse gas emissions from their flight.

⁵⁷⁷ Additionally, the Commission proposes advising offset marketers that they should not state or imply that their products have already reduced emissions or will do so in the near future if, in fact, the reductions will occur at a significantly later date.

well as rigorous tracking methods to ensure that the reductions are not sold more than once. Although savvy carbon offset marketers likely have these procedures in place already, the Commission proposes adding this point to the Guides to ensure that new market participants are fully informed of their responsibilities.

d. Substantiating Carbon Offset Claims – Additionality

Many aspects of the additionality debate raise unresolved technical and environmental policy issues. Because the Commission does not set environmental standards or policy, establishing a specific additionality test or tests appears to be outside of the FTC's purview. However, in accordance with its responsibility to ensure that consumers are not misled, the Commission proposes issuing guidance regarding regulatory additionality.

When consumers purchase carbon offsets, they expect that they are supporting a reduction in greenhouse gas emissions. If the law mandates a particular emission reduction, however, that reduction will occur whether or not someone buys an offset for the activity. In other words, if a company sells an offset based on a mandatory emission reduction, the purchaser is essentially funding that company's regulatory compliance activities.⁵⁷⁸ Therefore, in such situations, the proposed Guides advise marketers that offset sales are deceptive.⁵⁷⁹

The Commission does not propose promulgating guidance on which specific additionality tests sellers must meet to substantiate offset claims. Even if consumers have a vague expectation of "additionality," it is still unclear which test is appropriate to substantiate that interpretation.⁵⁸⁰ In addition, there is no consensus among experts in the field about which tests are appropriate. Of course, marketers are free to provide consumers with information about how and why their offset products are additional. While such disclosures may,

⁵⁷⁸ See Anadarko, Comment 533254-00058 at 5 (stating that it is reasonable for consumers to assume, absent any disclaimers to the contrary, that the GHG reduction was not taken to meet regulatory requirements).

⁵⁷⁹ The Commission notes that this guidance represents its interpretation of the FTC Act. In the future, other agencies may issue comprehensive carbon offset regulations that address these issues more specifically.

⁵⁸⁰ See Holt, Carbon Offsets Workshop Tr. at 165 (stating that consumers expect their carbon offset purchase to "make a difference," and that "making a difference means that it's additional to what would have happened otherwise," but noting that there is still a debate about how to determine what is additional); WRI, Carbon Offsets Workshop Tr. at 166.

or may not, be required to prevent deception, depending on the context, they may aid consumers in differentiating various offsets on the market.

e. Substantiating Carbon Offset Claims – Use of RECs

Similar to additionality, the use of RECs as a basis for offset claims involves unresolved technical and policy issues. These issues include the methods marketers should use to demonstrate that the RECs they purchase cause the claimed GHG reductions and which additionality tests they should apply. Further, it is unclear which entity owns the GHG reductions – the renewable energy generator or the fossil fuel-fired facility. Because of this uncertainty, there is a risk of double counting the emission reductions.

It is unlikely that the Commission can provide general guidance on these issues without setting environmental policy, which is beyond the agency's purview. Nevertheless, as with other environmental claims, marketers must substantiate their offset claims. Given the complexity of the issues related to the use of RECs as a basis for offsets, marketers should be cautious that they possess competent and reliable scientific evidence to substantiate their claims and ensure that the emission reductions are not double counted.

VII. Request for Comment

The Commission invites comment on all issues raised in this Notice, including all aspects of the proposed, revised Green Guides. In addition, the Commission requests responses to the following specific questions:

1. Do consumers interpret general environmental claims, when qualified by a particular attribute, to mean that the particular attribute provides the product with a net environmental benefit? Please provide any relevant consumer perception evidence. Should the Commission advise marketers that a qualified-general environmental claim is deceptive if a particular attribute represents an environmental improvement in one area, but causes a negative impact elsewhere that makes the product less environmentally beneficial than the product otherwise would be? Why or why not?
2. Would it be helpful to include an example in the Guides illustrating a qualified general environmental claim that is nevertheless deceptive? For example, a marketer advertises its product as "Eco-friendly sheets - made from bamboo." Consumers would likely interpret this claim to mean

- that the sheets are made from a natural fiber, using a process that is similar to that used for other natural fibers. The sheets, however, are actually a man-made fiber, rayon. Although bamboo can be used to make rayon, rayon is manufactured through a process that uses toxic chemicals and releases hazardous air pollutants. In this instance, the advertisement is deceptive.
3. The Commission's consumer perception study found that 27 percent of respondents interpreted the claims "green" and "eco-friendly" as suggesting that a product has no (rather than "some") negative impact. Viewing this finding alone, would it be deceptive for a product to be advertised with an unqualified general environmental benefit claim if the product had a negligible environmental impact? Please provide any relevant consumer perception evidence.
 4. If a marketer makes an unqualified degradable claim for a liquid substance (or dissolvable solid), how long do consumers believe the substance will take to completely degrade? Please provide any relevant consumer perception evidence. Should the Commission provide guidance concerning this time period in the Guides? Why or why not?
 5. The Commission proposes adopting a maximum period of one year for complete decomposition of solid materials marketed as degradable without time qualification. Would this guidance lead to deceptive claims in circumstances where consumers would expect a material to degrade in less than one year?
 6. Should the Commission quantify the "substantial majority" threshold in the recyclable section of the Guides? If so, how? If not, why not?
 7. Should the Commission quantify the "significant percentage" threshold in the recyclable section of the Guides? If so, how? If not, why not?
 8. What changes, if any, should the Commission make to its guidance on pre-consumer recycled content claims? How do consumers interpret such claims? Please provide any relevant consumer perception evidence.
 - a. If the Commission should retain its guidance that pre-consumer recycled materials be diverted from the solid waste stream: (1) should the Commission continue to consider "reuse in the original manufacturing process" and "significant reprocessing" to determine if material is diverted from the solid waste stream; (2) what factors should the Commission consider to determine whether material was diverted from the solid waste stream; and (3) when processes that divert material from the waste stream become standard practice in an industry, do consumers continue to consider that material recycled content?
 - b. If materials have historically been diverted from the solid waste stream and reused for one purpose (e.g., fiber fill in toys), but now may be reused for other higher purposes (e.g., as raw fiber for textiles), do consumers still consider that material to be recycled content even though the material was already being diverted from the solid waste stream?
 9. Do consumers understand the difference between pre-consumer and post-consumer recycled content? Please provide any relevant consumer perception evidence.
 10. Should the Commission continue to advise marketers that recycled content claims may be based on the annual weighted average of recycled content in an item? If so, why? If not, why not? Are recycled content claims based on this method likely to mislead consumers? Would qualifying the claim avoid that deception? If so, please describe what the disclosure should be, and why. Please also provide any relevant consumer perception evidence.
 11. If a product is advertised as "made with recycled materials," either in whole or in part, should the Commission advise marketers to qualify that claim to indicate that the product is not recyclable if it is not? Why or why not? If a disclosure is needed, please describe what the disclosure should be, and why.
 12. Are consumers aware that manufacturers are no longer permitted to use CFCs in their products? Do no-CFCs claims imply that other products still contain CFCs? Please provide any relevant consumer perception evidence.
 13. What guidance, if any, should the Commission provide concerning free-of claims based on substances which have never been associated with a product category? How do consumers understand such claims? Please provide any relevant consumer perception evidence.
 14. What guidance, if any, should the Commission provide concerning organic claims about non-agricultural products? How do consumers interpret organic claims for non-agricultural products? Do consumers understand such claims as referring to the products' ingredients, manufacturing, or processing, or all three? Please provide any relevant consumer perception evidence.
 15. How should marketers qualify "made with renewable materials" claims, if at all, to avoid deception? Does disclosing the type of material, how the material was sourced, and the reason the material is renewable adequately qualify the claim? Why or why not? Are there other disclosures that would adequately qualify a "made with renewable materials" claim? Please describe such disclosures. Please also provide any relevant consumer perception evidence.
 16. How, and under what circumstances, should marketers qualify "made with renewable energy" claims to avoid deception?
 - a. Does disclosing the source of the renewable energy adequately qualify the claim and prevent deceptive implications that the advertised product is made with renewable or recycled materials? Why or why not? Are there other disclosures that would adequately qualify a "made with renewable energy" claim? Please describe such disclosures. Please also provide any relevant consumer perception evidence.
 - b. Should the Commission advise marketers to qualify a "made with renewable energy" claim if the advertised product is not made entirely with renewable energy? If so, should marketers qualify such claims if all or virtually all significant processes used in making a product are powered by renewable energy? Why or why not? Please provide any relevant consumer perception evidence.
 17. How do consumers understand "carbon offset" and "carbon neutral" claims? Is there any evidence of consumer confusion concerning the use of these claims? Please provide any relevant consumer perception evidence.
 18. How should marketers qualify carbon offset claims, if at all, to avoid deception about the timing of emission reductions? Should marketers disclose if their offsets reflect emission reductions that are not scheduled to occur in two years? Should marketers make a disclosure if emission reductions are not scheduled to occur in some other time period? If so, what time period, and why? Would such a disclosure adequately qualify an offset claim to

avoid deception? Please provide any relevant consumer perception evidence about this issue or on carbon offsets, generally.

Interested parties are invited to submit written comments electronically or in paper form. Comments should state "Proposed, Revised Green Guides, 16 CFR Part 260, Project No. P954501" in the text and, if applicable, on the envelope.

The FTC will place your comment — including your name and your state — on the public record of this proceeding, and to the extent practicable, will make it available to the public on the FTC website at (<http://www.ftc.gov/os/publiccomments.shtml>). As a matter of discretion, the Commission endeavors to remove individuals' home contact information from the comments before placing them on its website. Because comments will be made public, they should not include: (1) any sensitive personal information, such as any individual'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; (2) any sensitive health information, such as medical records or other individually identifiable health information; or (3) any trade secret or any commercial or financial information which is privileged or confidential, as provided 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). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).⁵⁸¹

Because postal mail addressed to the FTC is subject to delay due to heightened security screening, if possible, please submit your comments in electronic form or send them by courier or overnight service. To ensure that the Commission considers an electronic comment, you must file it at (<https://ftcpublic.commentworks.com/ftc/revisedgreenguides>) by following the instructions on the web-based form. If this Notice appears at (<http://www.regulations.gov/search/Regs/home.html#home>), you may also file a comment through that website. The Commission will consider all comments

that www.regulations.gov forwards to it. You may also visit the FTC website at (<http://www.ftc.gov>) to read the Notice and the news release describing it.

A comment filed in paper form should include the reference "Proposed, Revised Green Guides, 16 CFR Part 260, Project No. P954501" in the text of the comment and, if applicable, on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

The FTC Act and other laws 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 comments it receives. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at (<http://www.ftc.gov/ftc/privacy.shtml>).

VIII. Proposed, Revised Green Guides

List of Subjects in 16 CFR Part 260

Advertising, Environmental protection, Labeling, Trade practices.

For the reasons set forth in the preamble, the Federal Trade Commission is proposing to revise 16 CFR Part 260 to read as follows:

PART 260—GUIDES FOR THE USE OF ENVIRONMENTAL MARKETING CLAIMS

Sec.

- 260.1 Purpose, scope, and structure of the guides.
- 260.2 Interpretation and substantiation of environmental marketing claims.
- 260.3 General principles.
- 260.4 General environmental benefit claims.
- 260.5 Carbon offsets.
- 260.6 Certifications and seals of approval.
- 260.7 Compostable claims.
- 260.8 Degradable claims.
- 260.9 Free-of and non-toxic claims.
- 260.10 Ozone-safe and ozone-friendly claims.
- 260.11 Recyclable claims.
- 260.12 Recycled content claims.
- 260.13 Refillable claims.
- 260.14 Renewable energy claims.
- 260.15 Renewable materials claims.
- 260.16 Source reduction claims.

Authority: 15 U.S.C. 41-58.

§ 260.1 Purpose, scope, and structure of the guides.

(a) These guides set forth the Federal Trade Commission's current thinking about environmental claims. The guides help marketers avoid making environmental marketing claims that are unfair or deceptive under Section 5 of

the Federal Trade Commission Act (FTC Act), 15 U.S.C.45. They do not confer any rights on any person and do not operate to bind the FTC or the public. The Commission, however, can take action under the FTC Act if a marketer makes an environmental claim inconsistent with the guides. In any such enforcement action, the Commission must prove that the challenged act or practice is unfair or deceptive in violation of Section 5 of the FTC Act.

(b) These guides do not preempt federal, state, or local laws. Compliance with those laws, however, will not necessarily preclude Commission law enforcement action under the FTC Act.

(c) These guides apply to claims about the environmental attributes of a product, package, or service in connection with the marketing, offering for sale, or sale of such item or service to individuals, businesses, or other entities. The guides apply to environmental claims in labeling, advertising, promotional materials, and all other forms of marketing in any medium, whether asserted directly or by implication, through words, symbols, logos, depictions, product brand names, or any other means.

(d) The guides consist of general principles, specific guidance on the use of particular environmental claims, and examples. Claims may raise issues that are addressed by more than one example and in more than one section of the guides. The examples provide the Commission's views on how reasonable consumers likely interpret certain claims. Marketers can use an alternative approach if the approach satisfies the requirements of Section 5 of the FTC Act. Whether a particular claim is deceptive will depend on the net impression of the advertisement, label, or other promotional material at issue. In addition, although many examples present specific claims and options for qualifying claims, the examples do not illustrate all permissible claims or qualifications under Section 5 of the FTC Act.

§ 260.2 Interpretation and substantiation of environmental marketing claims.

Section 5 of the FTC Act prohibits deceptive acts and practices in or affecting commerce. A representation, omission, or practice is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and is material to consumers' decisions. See FTC Policy Statement on Deception, 103 F.T.C. 174 (1983). To determine if an advertisement is deceptive, marketers must identify all express and implied claims that the advertisement

⁵⁸¹ The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The FTC's General Counsel will grant or deny the request consistent with applicable law and the public interest. See FTC Rule 4.9(c), 16 CFR 4.9(c).

reasonably conveys. Marketers must ensure that all reasonable interpretations of their claims are truthful, not misleading, and supported by a reasonable basis before they make the claims. See FTC Policy Statement Regarding Advertising Substantiation, 104 F.T.C. 839 (1984). In the context of environmental marketing claims, a reasonable basis often requires competent and reliable scientific evidence. Such evidence consists of tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results. Such evidence should be sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that each of the marketing claims is true.

§ 260.3 General principles.

The following general principles apply to all environmental marketing claims, including those described in §§ 260.4 through 260.16. Claims should comport with all relevant provisions of these guides.

(a) **Qualifications and disclosures:** To prevent deceptive claims, qualifications and disclosures should be clear, prominent, and understandable. To make disclosures clear and prominent, marketers should use plain language and sufficiently large type, should place disclosures in close proximity to the qualified claim, and should avoid making inconsistent statements or using distracting elements that could undercut or contradict the disclosure.

(b) **Distinction between benefits of product, package, and service:** Unless it is clear from the context, an environmental marketing claim should specify whether it refers to the product, the product's packaging, a service, or just to a portion of the product, package, or service. In general, if the environmental attribute applies to all but minor, incidental components of a product or package, the marketer need not qualify the claim to identify that fact. However, there may be exceptions to this general principle. For example, if a marketer makes an unqualified recyclable claim, and the presence of the incidental component significantly limits the ability to recycle the product, the claim would be deceptive.

Example 1: A plastic package containing a new shower curtain is labeled "recyclable" without further elaboration. Because the context of

the claim does not make clear whether it refers to the plastic package or the shower curtain, the claim is deceptive if any part of either the package or the curtain, other than minor, incidental components, cannot be recycled.

Example 2: A soft drink bottle is labeled "recycled." The bottle is made entirely from recycled materials, but the bottle cap is not. Because the bottle cap is a minor, incidental component of the package, the claim is not deceptive.

(c) **Overstatement of environmental attribute:** An environmental marketing claim should not overstate, directly or by implication, an environmental attribute or benefit. Marketers should not state or imply environmental benefits if the benefits are negligible.

Example 1: An area rug is labeled "50% more recycled content than before." The manufacturer increased the recycled content of its rug from 2% recycled fiber to 3%. Although the claim is technically true, it likely conveys the false impression that the manufacturer has increased significantly the use of recycled fiber.

Example 2: A trash bag is labeled "recyclable" without qualification. Because trash bags ordinarily are not separated from other trash at the landfill or incinerator for recycling, they are highly unlikely to be used again for any purpose. Even if the bag is technically capable of being recycled, the claim is deceptive since it asserts an environmental benefit where no meaningful benefit exists.

(d) **Comparative claims:** Comparative environmental marketing claims should be clear to avoid consumer confusion about the comparison. Marketers should have substantiation for the comparison.

Example 1: An advertiser notes that its glass bathroom tiles contain "20% more recycled content." Depending on the context, the claim could be a comparison either to the advertiser's immediately preceding product or to its competitors' products. The advertiser should have substantiation for both interpretations. Otherwise, the advertiser should make the basis for comparison clear, for example, by saying "20% more recycled content than our previous bathroom tiles."

Example 2: An advertiser claims that "our plastic diaper liner has the most recycled content." The diaper liner has more recycled content, calculated as a percentage of weight, than any other on the market, although it is still well under 100%. The claim likely conveys that the product contains a

significant percentage of recycled content and has significantly more recycled content than its competitors. If the advertiser cannot substantiate these messages, the claim would be deceptive.

Example 3: An advertiser claims that its packaging creates "less waste than the leading national brand." The advertiser implemented the source reduction several years ago and supported the claim by calculating the relative solid waste contributions of the two packages. The advertiser should have substantiation that the comparison remains accurate.

Example 4: A product is advertised as "environmentally preferable." This claim likely conveys that the product is environmentally superior to other products. Because it is highly unlikely that the marketer can substantiate the messages conveyed by this statement, this claim is deceptive. The claim would not be deceptive if the marketer accompanied it with clear and prominent language limiting the environmental superiority representation to the particular attributes for which the marketer has substantiation, provided the advertisement's context does not imply other deceptive claims. For example, the claim "Environmentally preferable: contains 50% recycled content compared to 20% for the leading brand" would not be deceptive.

§ 260.4 General environmental benefit claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product, package, or service offers a general environmental benefit.

(b) Unqualified general environmental benefit claims are difficult to interpret and likely convey a wide range of meanings. In many cases, such claims likely convey that the product, package, or service has specific and far-reaching environmental benefits and may convey that the item or service has no negative environmental impact. Because it is highly unlikely that marketers can substantiate all reasonable interpretations of these claims, marketers should not make unqualified general environmental benefit claims.

(c) Marketers can qualify general environmental benefit claims to prevent deception about the nature of the environmental benefit being asserted. To avoid deception, marketers should use clear and prominent qualifying language that limits the claim to a specific benefit.

(d) Even if a marketer explains, and has substantiation for, the product's specific environmental attributes, this explanation will not adequately qualify a general environmental benefit claim if the advertisement otherwise implies deceptive claims. Therefore, marketers should ensure that the advertisement's context does not imply deceptive environmental claims.

Example 1: The brand name "Eco-friendly" likely conveys that the product has far-reaching environmental benefits and may convey that the product has no negative environmental impact. Because it is highly unlikely that the marketer can substantiate these claims, the use of such a brand name is deceptive. A claim, such as "Eco-friendly: made with recycled materials," would not be deceptive if the statement "made with recycled materials" is clear and prominent; the marketer has substantiation for the statement; and provided that the advertisement's context does not imply other deceptive claims.

Example 2: A product wrapper bears the claim "Environmentally Friendly." Text on the wrapper explains that it is environmentally friendly because it was "not chlorine bleached, a process that has been shown to create harmful substances." Although the wrapper was not bleached with chlorine, its production releases into the environment other harmful substances. Since reasonable consumers likely would interpret the "Environmentally Friendly" claim, in combination with the explanation, to mean that no significant harmful substances are released into the environment, the "Environmentally Friendly" claim is deceptive.

Example 3: A marketer states that its packaging is now "Greener than our previous packaging." The packaging weighs 15% less than previous packaging, but it is not recyclable nor has it been improved in any other material respect. The claim is deceptive because reasonable consumers likely would interpret "Greener" in this context to mean that other significant environmental aspects of the packaging also are improved over previous packaging. A claim stating "Greener than our previous packaging" accompanied by clear and prominent language such as, "We've reduced the weight of our packaging by 15%," would not be deceptive, provided that the advertisement's context does not imply other deceptive claims.

§ 260.5 Carbon offsets.

(a) Given the complexities of carbon offsets, sellers should employ competent and reliable scientific and accounting methods to properly quantify claimed emission reductions and to ensure that they do not sell the same reduction more than one time.

(b) It is deceptive to misrepresent, directly or by implication, that a carbon offset represents emission reductions that have already occurred or will occur in the immediate future. To avoid deception, marketers should clearly and prominently disclose if the carbon offset represents emission reductions that will not occur for two years or longer.

(c) It is deceptive to claim, directly or by implication, that a carbon offset represents an emission reduction if the reduction, or the activity that caused the reduction, was required by law.

Example 1: On its website, an airline invites consumers to purchase offsets to "neutralize the carbon emissions from your flight." The proceeds from the offset sales fund future projects that will not reduce greenhouse gas emissions for two years. The claim likely conveys that the emission reductions either already have occurred or will occur in the near future. Therefore, the advertisement is deceptive. It would not be deceptive if the airline's website stated "Offset the carbon emissions from your flight by funding new projects that will begin reducing emissions in two years."

Example 2: An offset provider claims that its product "will offset your own 'dirty' driving habits." The offset is based on methane capture at a landfill facility. State law requires this facility to capture all methane emitted from the landfill. The claim is deceptive because the emission reduction would have occurred regardless of whether consumers purchased the offsets.

§ 260.6 Certifications and seals of approval.

(a) It is deceptive to misrepresent, directly or by implication, that a product, package, or service has been endorsed or certified by an independent third-party.

(b) A marketer's use of the name, logo, or seal of approval of a third-party certifier is an endorsement, which should meet the criteria for endorsements provided in the FTC's Endorsement Guides, 16 CFR Part 255, including Definitions (§ 255.0), General Considerations (§ 255.1), Expert Endorsements (§ 255.3), Endorsements by Organizations (§ 255.4), and

Disclosure of Material Connections (§ 255.5).

(c) Third-party certification does not eliminate a marketer's obligation to ensure that it has substantiation for all claims reasonably communicated by the certification.

(d) A marketer's use of an unqualified environmental certification or seal of approval (*i.e.*, one that does not state the basis for the certification) likely conveys a general environmental benefit claim (addressed in § 260.4). Because it is highly unlikely that marketers can substantiate such claims, marketers should not use unqualified certifications or seals of approval.

(e) To avoid deception, language qualifying a certification or seal of approval should be clear and prominent and should clearly convey that the certification or seal of approval refers only to specific and limited benefits. This qualifying language may be part of the certification or seal itself.

Example 1: An advertisement for paint features a "GreenLogo" seal and the statement "GreenLogo for Environmental Excellence." This advertisement likely conveys that: the GreenLogo seal is awarded by an independent, third-party certifier with expertise in evaluating the environmental attributes of paint; and the product has far-reaching environmental benefits. If the paint manufacturer placed the GreenLogo seal in its advertisement, and no independent, third-party certifier evaluated the paint, the claim would be deceptive. The claim would not be deceptive if the marketer accompanied the seal with clear and prominent language: indicating that the marketer itself created the GreenLogo seal; and limiting the general environmental benefit representation to the particular product attributes for which the marketer has substantiation, provided that the advertisement's context does not imply other deceptive claims.

Example 2: A product advertisement includes a seal with the text "Certified by the Renewable Energy Association." The product manufacturer is a dues-paying member of that association. Even if the association certified that the manufacturer uses only renewable energy, the use of the seal is deceptive because it likely conveys that the association is independent from the product manufacturer. To avoid deception, the manufacturer should accompany the seal with clear and prominent language disclosing the material connection.

Example 3: A manufacturer advertises its product as “certified by the American Institute of Degradable Materials.” The advertisement does not mention that the American Institute of Degradable Materials is an industry trade association. Regardless of whether the manufacturer is a member, this advertisement is deceptive because it likely conveys that the product is certified by an independent certifying organization, not an industry group. The advertisement would not be deceptive if the manufacturer accompanies its statement that the product is “certified by the American Institute of Degradable Materials” with clear and prominent language indicating that the Institute is an industry trade association, and if the manufacturer otherwise complies with § 260.8 of the Guides.

Example 4: A marketer’s industry sales brochure for overhead lighting features a seal with the text “U.S. EcoFriendly Building Association” to show that the marketer is a member of that organization. Although the lighting manufacturer is, in fact, a member, this association has not evaluated the environmental attributes of the company’s product. This advertisement would be deceptive because it likely conveys that the U.S. EcoFriendly Building Association evaluated the product through testing or other objective standards. It also is likely to convey that the lighting has far-reaching environmental benefits. The use of the seal would not be deceptive if the manufacturer accompanies it with clear and prominent qualifying language: indicating that the seal refers to the company’s membership only and that the association did not evaluate the product’s environmental attributes, and limiting the general environmental benefit representation to the particular product attributes for which the marketer has substantiation, provided that the advertisement’s context does not imply other deceptive claims. For example, the marketer could state, “Although we are a member of the U.S. EcoFriendly Building Association, it has not evaluated this product. Our lighting is made from 100 percent recycled metal and uses energy efficient LED technology.”

Example 5: A product label contains an environmental seal, either in the form of a globe icon or a globe icon with the text “EarthSmart.” EarthSmart is an independent, third-party certifier that uses standards

previously adopted by EarthSmart and suitable for evaluating products’ chemical emissions. While the marketer meets EarthSmart’s standards for reduced chemical emissions during product usage, the product has no other specific environmental benefits. Either seal likely conveys that the product has far-reaching environmental benefits, and that Earth Smart certified the product for all of these benefits. If the marketer cannot substantiate these claims, the use of the seal would be deceptive. The seal would not be deceptive if the marketer accompanied it with clear and prominent language limiting the general environmental benefit claim to the particular product attributes for which the manufacturer has substantiation, provided that the advertisement’s context does not imply other deceptive claims. For example, the marketer could state next to the globe icon: “EarthSmart certifies that this product meets EarthSmart standards for reduced chemical emissions during product usage.” Alternatively, the claim would not be deceptive if the EarthSmart environmental seal itself stated: “EarthSmart Certified for reduced chemical emissions during product usage.”

Example 6: Great Paper Company sells photocopy paper with packaging that has a seal of approval from the No Chlorine Products Association, a non-profit third-party association. There are no material connections between Great Paper Company and the No Chlorine Products Association. Using standards widely recognized by industry experts, the No Chlorine Products Association certifies that products are chlorine-free. Moreover, the Association’s endorsement was reached by a process sufficient to ensure that the endorsement fairly reflects the collective judgment of the Association. The claim would not be deceptive.

§ 260.7 Compostable claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is compostable.

(b) A marketer claiming that an item is compostable should have competent and reliable scientific evidence that all the materials in the item will break down into, or otherwise become part of, usable compost (*e.g.*, soil-conditioning material, mulch) in a safe and timely manner (*i.e.*, in approximately the same time as the materials with which it is

composted) in an appropriate composting program or facility or in a home compost pile or device.

(c) A marketer should clearly and prominently qualify compostable claims to the extent necessary to avoid deception if: the item cannot be composted safely or in a timely manner in a home compost pile or device; or the claim misleads reasonable consumers about the environmental benefit provided when the item is disposed of in a landfill.

(d) To avoid deception about the limited availability of municipal or institutional composting facilities, a marketer should clearly and prominently qualify compostable claims if such facilities are not available to a substantial majority of consumers or communities where the item is sold.

Example 1: A manufacturer indicates that its unbleached coffee filter is compostable. The unqualified claim is not deceptive, provided the manufacturer has substantiation that the filter can be converted safely to usable compost in a timely manner in a home compost pile or device. If so, the extent of local municipal or institutional composting facilities is irrelevant.

Example 2: A garden center sells grass clipping bags labeled as “Compostable in California Municipal Yard Trimmings Composting Facilities.” When the bags break down, however, they release toxins into the compost. The claim is deceptive if the presence of these toxins prevents the compost from being usable.

Example 3: An electronics manufacturer makes an unqualified claim that its package is compostable. Although municipal or institutional composting facilities exist where the product is sold, the package will not break down into usable compost in a home compost pile or device. To avoid deception, the manufacturer should clearly and prominently disclose that the package is not suitable for home composting.

Example 4: Nationally marketed lawn and leaf bags state “compostable” on each bag. The bags also feature text disclosing that the bag is not designed for use in home compost piles. Yard trimmings programs in many communities compost these bags, but such programs are not available to a substantial majority of consumers or communities where the bag is sold. The claim is deceptive because it likely conveys that composting facilities are available to a substantial

majority of consumers or communities. To avoid deception, the marketer should clearly and prominently indicate the limited availability of such programs. A marketer could state "Appropriate facilities may not exist in your area," or provide the approximate percentage of communities or consumers for which such programs are available.

Example 5: A manufacturer sells a disposable diaper that states, "This diaper can be composted if your community is one of the 50 that have composting facilities." The claim is not deceptive if composting facilities are available as claimed and the manufacturer has substantiation that the diaper can be converted safely to usable compost in solid waste composting facilities.

Example 6: A manufacturer markets yard trimmings bags only to consumers residing in particular geographic areas served by county yard trimmings composting programs. The bags meet specifications for these programs and are labeled, "Compostable Yard Trimmings Bag for County Composting Programs." The claim is not deceptive. Because the bags are compostable where they are sold, a qualification is not needed to indicate the limited availability of composting facilities.

§ 260.8 Degradable claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is degradable, biodegradable, oxo-degradable, oxo-biodegradable, or photodegradable. The following guidance for degradable claims also applies to biodegradable, oxo-degradable, oxo-biodegradable, or photodegradable claims.

(b) A marketer making an unqualified degradable claim should have competent and reliable scientific evidence that the entire item will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within a reasonably short period of time after customary disposal.

(c) It is deceptive to make an unqualified degradable claim for solid items if the items do not completely decompose within one year after customary disposal. Unqualified degradable claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year.

(d) Degradable claims should be qualified clearly and prominently to the extent necessary to avoid deception about: the product or package's ability to degrade in the environment where it is customarily disposed; and the rate and extent of degradation.

Example 1: A marketer advertises its trash bags using an unqualified "degradable" claim. The marketer relies on soil burial tests to show that the product will decompose in the presence of water and oxygen. Consumers, however, customarily dispose of trash bags in incineration facilities or landfills where they will not degrade within one year. The claim is, therefore, deceptive.

Example 2: A marketer advertises a commercial agricultural plastic mulch film with the claim "Photodegradable," and clearly and prominently qualifies the term with the phrase "Will break down into small pieces if left uncovered in sunlight." The advertiser possesses competent and reliable scientific evidence that within one year, the product will break down after being exposed to sunlight and into sufficiently small pieces to become part of the soil. Thus, the qualified claim is not deceptive. Because the claim is qualified to indicate the limited extent of breakdown, the advertiser need not meet the consumer expectations for an unqualified photodegradable claim, *i.e.*, that the product will not only break down, but also will decompose into elements found in nature.

Example 3: A marketer advertises its shampoo as "biodegradable" without qualification. The advertisement makes clear that only the shampoo, and not the bottle, is biodegradable. The marketer has competent and reliable scientific evidence demonstrating that the shampoo, which is customarily disposed in sewage systems, will break down and decompose into elements found in nature in a reasonably short period of time in the sewage system environment. Therefore, the claim is not deceptive.

Example 4: A plastic six-pack ring carrier is marked with a small diamond. Several state laws require that the carriers be marked with this symbol to indicate that they meet certain degradability standards if the carriers are littered. The use of the

diamond, by itself, does not constitute a degradable claim.¹

Example 5: A fiber pot containing a plant is labeled "biodegradable." The pot is customarily buried in the soil along with the plant. Once buried, the pot fully decomposes during the growing season, allowing the roots of the plant to grow into the surrounding soil. The unqualified claim is not deceptive.

§ 260.9 Free-of and non-toxic claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product, package, or service is free of, or does not contain or use, a substance or that a product, package, or service is non-toxic. Such claims should be clearly and prominently qualified to the extent necessary to avoid deception.

(b) A truthful claim that a product, package, or service is free of, or does not contain or use, a substance may nevertheless be deceptive if: the product, package, or service contains or uses substances that pose the same or similar environmental risks as the substance that is not present; or the substance has never been associated with the product category.

(c) Depending on the context, some no, free-of, or does-not-contain claims may be appropriate even where a product, package, or service contains or uses a *de minimis* amount of a substance.

(d) A marketer that makes a no, free-of, or does-not-contain claim that reasonable consumers would interpret to convey additional environmental claims, including general environmental benefit claims or comparative superiority claims, must have substantiation for each such claim.

(e) A non-toxic claim likely conveys that a product, package, or service is non-toxic both for humans and for the environment generally. Therefore, marketers making non-toxic claims should have competent and reliable scientific evidence that the product, package, or service is non-toxic for humans and for the environment or should clearly and prominently qualify their claims to avoid deception.

Example 1: A package of t-shirts is labeled "Shirts made with a chlorine-free bleaching process." The shirts, however, are bleached with a process that releases a reduced, but still significant, amount of the same harmful byproducts associated with

¹ The guides' treatment of unqualified degradable claims is intended to help prevent deception and is not intended to establish performance standards to ensure the degradability of products when littered.

chlorine bleaching. The claim overstates the product's benefits because reasonable consumers likely would interpret it to mean that the product's manufacture does not cause any of the environmental risks posed by chlorine bleaching. A claim, however, that the shirts were "bleached with a process that substantially reduces harmful substances associated with chlorine bleaching" would not be deceptive, if substantiated.

Example 2: A manufacturer advertises its insulation as "formaldehyde free." Although the manufacturer does not use formaldehyde as a binding agent to produce the insulation, tests show that the insulation still emits trace amounts of formaldehyde. The seller has substantiation that formaldehyde is present in trace amounts in virtually all indoor and (to a lesser extent) outdoor environments and that its insulation emits less formaldehyde than is typically present in outdoor environments. In this context, the trace levels of formaldehyde emissions likely are inconsequential to consumers. Therefore, the seller's free-of claim would not be deceptive.

Example 3: A marketer advertises a lawn care product as "essentially non-toxic" and "practically non-toxic." The advertisement likely conveys that the product does not pose any risk to humans or the environment. If the pesticide poses no risk to humans but is toxic to the environment, the claims would be deceptive.

§ 260.10 Ozone-safe and ozone-friendly claims.

It is deceptive to misrepresent, directly or by implication, that a product, package, or service is safe for, or friendly to, the ozone layer or the atmosphere.

Example 1: A product is labeled "ozone friendly." The claim is deceptive if the product contains any ozone-depleting substance, including those substances listed as Class I or Class II chemicals in Title VI of the Clean Air Act Amendments of 1990, Pub. L. No. 101-549, and others subsequently designated by EPA as ozone-depleting substances. These chemicals include chlorofluorocarbons (CFCs), halons, carbon tetrachloride, 1,1,1-trichloroethane, methyl bromide, hydrobromofluorocarbons, and hydrochlorofluorocarbons (HCFCs).

Example 2: An aerosol air freshener is labeled "ozone friendly." Some of the

product's ingredients are volatile organic compounds (VOCs) that may cause smog by contributing to ground-level ozone formation. The claim likely conveys that the product is safe for the atmosphere as a whole, and, therefore, is deceptive.

Example 3: A manufacturer has substituted non-ozone-depleting refrigerants for the ozone-depleting substances in its residential air conditioning equipment. The manufacturer advertises its equipment as "environmentally friendly." This general environmental benefit claim likely conveys that the product has far reaching environmental benefits. However, the manufacturer's air conditioning equipment consumes a substantial amount of energy and relies on refrigerants that are greenhouse gases. Accordingly, this claim is deceptive.

§ 260.11 Recyclable claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is recyclable. A product or package should not be marketed as recyclable unless it can be collected, separated, or otherwise recovered from the solid waste stream through an established recycling program for reuse or use in manufacturing or assembling another item.

(b) Marketers should clearly and prominently qualify recyclable claims to the extent necessary to avoid deception about the availability of recycling programs and collection sites to consumers.

(1) When recycling facilities are available to a substantial majority² of consumers or communities where the item is sold, marketers can make unqualified recyclable claims.

(2) When recycling facilities are available to a significant percentage of consumers or communities where the item is sold, but not to a substantial majority, marketers should clearly and prominently qualify their recyclable claims. Suggested qualifications are: "This product [package] may not be recyclable in your area," "Recycling programs for this product [package] may not exist in your area," or a statement of the percentage of communities or the population that have programs where the item can be recycled.

(3) When recycling facilities are available to less than a significant percentage of consumers or communities where the item is sold,

marketers should clearly and prominently qualify their recyclable claims. Suggested qualifications are: "This product [package] is recyclable only in the few communities that have recycling programs," or a statement of the percentage of communities or the population that have programs where the item can be recycled.

(c) Marketers can make unqualified recyclable claims for a product or package if the entire product or package, excluding minor incidental components, is recyclable. For items that are partially made of recyclable components, marketers should clearly and prominently qualify the recyclable claim to avoid deception about which portions are recyclable.

(d) If any component significantly limits the ability to recycle the item, any recyclable claim would be deceptive. An item that is made from recyclable material, but, because of its shape, size, or some other attribute, is not accepted in recycling programs, should not be marketed as recyclable.³

Example 1: A packaged product is labeled with an unqualified claim, "recyclable." It is unclear from the type of product and other context whether the claim refers to the product or its package. The unqualified claim likely conveys that both the product and its packaging, except for minor, incidental components, can be recycled. Unless the manufacturer has substantiation for both messages, it should clearly and prominently qualify the claim to indicate which portions are recyclable.

Example 2: A nationally marketed plastic yogurt container displays the Society of the Plastics Industry (SPI) code (which consists of a design of arrows in a triangular shape containing a number in the center and an abbreviation identifying the component plastic resin) on the front label of the container, in close proximity to the product name and logo. This conspicuous use of the SPI code constitutes a recyclable claim. Unless recycling facilities for this container are available to a substantial majority of consumers or communities, the manufacturer should qualify the claim to disclose the limited availability of recycling programs. If the manufacturer places the SPI code, without more, in an

² Commission staff has informally interpreted the term "substantial majority," as used in this context, to mean at least 60 percent.

³ Batteries labeled in accordance with the Mercury-Containing and Rechargeable Battery Management Act, 42 U.S.C. § 14322(b), are deemed to be in compliance with these Guides.

inconspicuous location on the container (e.g., embedded in the bottom of the container), it would not constitute a recyclable claim.

Example 3: A container can be burned in incinerator facilities to produce heat and power. It cannot, however, be recycled into another product or package. Any claim that the container is recyclable would be deceptive.

Example 4: A paperboard package is marketed nationally and labeled either “Recyclable where facilities exist” or “Recyclable – Check to see if recycling facilities exist in your area.” Recycling programs for these packages are available to a significant percentage of the population, but not to a substantial majority of consumers nationwide. Both claims are deceptive because they do not adequately disclose the limited availability of recycling programs. To avoid deception, the marketer should use a clearer qualification, such as those suggested in § 260.11(b)(2).

Example 5: Foam polystyrene cups are advertised as “Recyclable in the few communities with facilities for foam polystyrene cups.” A half-dozen major metropolitan areas have established collection sites for recycling those cups. The claim is not deceptive because it clearly discloses the limited availability of recycling programs.

Example 6: A package is labeled “Includes some recyclable material.” The package is composed of four layers of different materials, bonded together. One of the layers is made from recyclable material, but the others are not. While programs for recycling this type of package are available to a substantial majority of consumers, only a few of those programs have the capability to separate the recyclable layer from the non-recyclable layers. Even though it is technologically possible to separate the layers, the claim is deceptive. An appropriately qualified claim would be “Includes material recyclable in the few communities that can process multi-layer products.”

Example 7: A product container is labeled “recyclable.” The marketer advertises and distributes the product only in Missouri. Collection sites for recycling the container are available to a substantial majority of Missouri residents but are not yet available nationally. Because programs are generally available where the product

is sold, the unqualified claim is not deceptive.

Example 8: A manufacturer of one-time use cameras, with dealers in a substantial majority of communities, operates a take-back program that collects those cameras through all of its dealers. The manufacturer reconditions the cameras for resale and labels them “Recyclable through our dealership network.” This claim is not deceptive, even though the cameras are not recyclable through conventional curbside or drop off recycling programs.

Example 9: A manufacturer advertises its toner cartridges for computer printers as “Recyclable. Contact your local dealer for details.” Although all of the company’s dealers recycle cartridges, the dealers are not located in a substantial majority of communities where cartridges are sold. Therefore, the claim is deceptive. If dealers are located in a significant number of communities, the manufacturer should qualify its claim as suggested in § 260.11(b)(2). If participating dealers are located in only a few communities, the manufacturer should qualify the claim as suggested in § 260.11(b)(3).

Example 10: An aluminum can is labeled “Please Recycle.” This statement likely conveys that the can is recyclable. If collection sites for recycling these cans are available to a substantial majority of consumers or communities, the marketer does not need to qualify the claim.

§ 260.12 Recycled content claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is made of recycled content. Recycled content includes recycled raw material, as well as used,⁴ reconditioned, and re-manufactured components.

(b) It is deceptive to represent, directly or by implication, that an item contains recycled content unless it is composed of materials that have been recovered or otherwise diverted from the solid waste stream, either during the manufacturing process (pre-consumer), or after consumer use (post-consumer). If the source of recycled content includes pre-consumer material, the advertiser should have substantiation that the pre-consumer material would otherwise have entered the solid waste stream. Recycled content claims may –

but do not have to – distinguish between pre-consumer and post-consumer materials. Where a marketer distinguishes between pre-consumer and post-consumer materials, it should have substantiation for any express or implied claim about the percentage of pre-consumer or post-consumer content in an item.

(c) Marketers can make unqualified claims of recycled content if the entire product or package, excluding minor, incidental components, is made from recycled material. For items that are partially made of recycled material, the marketer should clearly and prominently qualify the claim to avoid deception about the amount or percentage, by weight, of recycled content in the finished product or package.

(d) For products that contain used, reconditioned, or re-manufactured components, the marketer should clearly and prominently qualify the recycled content claim to avoid deception about the nature of such components. No such qualification is necessary where it is clear to reasonable consumers from context that a product’s recycled content consists of used, reconditioned, or re-manufactured components.

Example 1: A manufacturer collects spilled raw material and scraps from the original manufacturing process. After a minimal amount of reprocessing, the manufacturer combines the spills and scraps with virgin material for use in production of the same product. A recycled content claim is deceptive since the spills and scraps are normally reused by industry within the original manufacturing process and would not normally have entered the waste stream.

Example 2: A manufacturer purchases material from a firm that collects discarded material from other manufacturers and resells it. All of the material was diverted from the solid waste stream and is not normally reused by industry within the original manufacturing process. The manufacturer includes the weight of this material in its calculations of the recycled content of its products. It would not be deceptive for the manufacturer to advertise the amount of recycled content in its product because, absent the purchase and reuse of this material, it would have entered the solid waste stream.

Example 3: Fifty percent (50%) of a greeting card’s fiber weight is

⁴ The term “used” refers to parts that are not new and that have not undergone any re-manufacturing or reconditioning.

composed from paper that was diverted from the solid waste stream. Of this material, 30% is post-consumer and 20% is pre-consumer. It would not be deceptive if the marketer claimed that the card either “contains 50% recycled fiber” or “contains 50% total recycled fiber, including 30% post-consumer fiber.”

Example 4: A paperboard package with 20% recycled fiber by weight is labeled “20% post-consumer recycled fiber.” The recycled content was composed of overrun newspaper stock never sold to customers. Because the newspapers never reached consumers, the claim is deceptive.

Example 5: A product in a multi-component package, such as a paperboard box in a shrink-wrapped plastic cover, indicates that it has recycled packaging. The paperboard box is made entirely of recycled material, but the plastic cover is not. The claim is deceptive because, without qualification, it suggests that both components are recycled. A claim limited to the paperboard box would not be deceptive.

Example 6: A manufacturer makes a package from laminated layers of foil, plastic, and paper, although the layers are indistinguishable to consumers. The label claims that “one of the three layers of this package is made of recycled plastic.” The plastic layer is made entirely of recycled plastic. The claim is not deceptive, provided the recycled plastic layer constitutes a significant component of the entire package.

Example 7: A frozen dinner package is composed of a plastic tray inside a cardboard box. It states “package made from 30% recycled material.” Each packaging component is one-half the weight of the total package. The box is 20% recycled content by weight, while the plastic tray is 40% recycled content by weight. The claim is not deceptive, since the average amount of recycled material is 30%.

Example 8: A manufacturer labels a paper greeting card “50% recycled fiber.” The manufacturer purchases paper stock from several sources, and the amount of recycled fiber in the stock provided by each source varies. If the 50% figure is based on the annual weighted average of recycled material purchased from the sources after accounting for fiber loss during the production process, the claim is not deceptive.

Example 9: A packaged food product is labeled with a three-chasing-arrows symbol (a Möbius loop) without explanation. By itself, the symbol likely conveys that the packaging is both recyclable and made entirely from recycled material. Unless the marketer has substantiation for both messages, the claim should be qualified. The claim may need to be further qualified, to the extent necessary, to disclose the limited availability of recycling programs and/or the percentage of recycled content used to make the package.

Example 10: In an office supply catalog, a manufacturer advertises its printer toner cartridges “65% recycled.” The cartridges contain 25% recycled raw materials and 40% reconditioned parts. The claim is deceptive because reasonable consumers likely would not know or expect that a cartridge’s recycled content consists of reconditioned parts. It would not be deceptive if the manufacturer claimed “65% recycled content; including 40% from reconditioned parts.”

Example 11: A store sells both new and used sporting goods. One of the items for sale in the store is a baseball helmet that, although used, is no different in appearance than a brand new item. The helmet bears an unqualified “Recycled” label. This claim is deceptive because reasonable consumers likely would believe that the helmet is made of recycled raw materials, when it is, in fact, a used item. An acceptable claim would bear a disclosure clearly and prominently stating that the helmet is used.

Example 12: An automotive dealer recovers a serviceable engine from a wrecked vehicle. Without repairing, rebuilding, re-manufacturing, or in any way altering the engine or its components, the dealer attaches a “Recycled” label to the engine, and offers it for sale in its used auto parts store. In this situation, an unqualified recycled content claim likely is not deceptive because reasonable consumers likely would understand that the engine is used and has not undergone any rebuilding.

Example 13: An automobile parts dealer purchases a transmission that has been recovered from a junked vehicle. Eighty-five percent of the transmission, by weight, was rebuilt and 15% constitutes new materials. After rebuilding⁵ the transmission in

accordance with industry practices, the dealer packages it for resale in a box labeled “Rebuilt Transmission,” or “Rebuilt Transmission (85% recycled content from rebuilt parts),” or “Recycled Transmission (85% recycled content from rebuilt parts).” These claims are not deceptive.

§ 260.13 Refillable claims.

It is deceptive to misrepresent, directly or by implication, that a package is refillable. A marketer should not make an unqualified refillable claim unless the marketer provides the means for refilling the package. The marketer may either provide a system for the collection and refill of the package, or offer for sale a product that consumers can purchase to refill the original package.

Example 1: A container is labeled “refillable three times.” The manufacturer has the capability to refill returned containers and can show that the container will withstand being refilled at least three times. The manufacturer, however, has established no collection program. The unqualified claim is deceptive because there is no means to return the container to the manufacturer for refill.

Example 2: A small bottle of fabric softener states that it is in a “handy refillable container.” In the same market area, the manufacturer also sells a large-sized bottle that consumers use to refill the smaller bottles. The claim is not deceptive because there is a reasonable means for the consumer to refill the smaller container.

§ 260.14 Renewable energy claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is made with renewable energy or that a service uses renewable energy. Marketers should not make unqualified renewable energy claims, directly or by implication, if power derived from fossil fuels is used to manufacture any part of the advertised item or is used to power any part of the advertised service.

(b) Research suggests that reasonable consumers may interpret renewable energy claims differently than marketers may intend. Unless marketers have substantiation for all their express and reasonably implied claims, they should

necessary, cleaned all of its internal and external parts and eliminated rust and corrosion, restored all impaired, defective or substantially worn parts to a sound condition (or replaced them if necessary), and performed any operations required to put the transmission in sound working condition.

⁵ The term “rebuilding” means that the dealer dismantled and reconstructed the transmission as

clearly and prominently qualify their renewable energy claims by specifying the source of the renewable energy (e.g., wind or solar energy).

(c) It is deceptive to make an unqualified “made with renewable energy” claim unless all or virtually all of the significant manufacturing processes involved in making the product or package are powered with renewable energy or conventional energy offset by renewable energy certificates.

(d) If a marketer generates renewable electricity but sells renewable energy certificates for all of that electricity, it would be deceptive for the marketer to represent, directly or by implication, that it uses renewable energy.

Example 1: A marketer advertises its clothing line as “made with wind power.” The marketer buys renewable energy certificates to match only 50% of the energy it uses. The marketer’s claim is deceptive because reasonable consumers likely interpret the claim to mean that the power was composed entirely of renewable energy. If the marketer stated “we purchase wind energy for half of our manufacturing facilities,” the claim would not be deceptive.

Example 2: A company places solar panels on its store roof to generate power and advertises that its store is “100% solar-powered.” The company, however, sells renewable energy certificates based on the renewable attributes of all the power it generates. Even if the company uses the electricity generated by the solar panels, it has, by selling renewable energy certificates, transferred the right to characterize that electricity as renewable. The company’s claim is therefore deceptive. It also would be deceptive for this company to advertise that it “hosts a renewable power facility” because reasonable consumers likely would interpret this claim to mean that the company uses renewable energy.

§ 260.15 Renewable materials claims.

(a) It is deceptive to misrepresent, directly or by implication, that a product or package is made with renewable materials.

(b) Research suggests that reasonable consumers may interpret renewable materials claims differently than marketers may intend. For example, reasonable consumers may believe an item advertised as being “made with renewable materials” is made with recycled content, recyclable, and biodegradable. Unless marketers have substantiation for all their express and reasonably implied claims, they should clearly and prominently qualify their renewable materials claims by specifying the material used, how the material is sourced, and why the material is renewable.

(c) It is deceptive to make an unqualified “made with renewable materials” claim unless the product or package (excluding minor, incidental components) is made entirely with renewable materials.

Example 1: A marketer makes the unqualified claim that its flooring is “made with renewable materials.” Reasonable consumers likely interpret this claim to mean that the flooring also is made with recycled content, recyclable, and biodegradable. Unless the marketer has substantiation for these implied claims, the unqualified “made with renewable materials” claim is deceptive. The marketer could qualify the claim by stating, clearly and prominently, “Our flooring is made from 100% bamboo, a fast-growing plant, which we cultivate at the same rate, or faster, than we use it.”

Example 2: A marketer’s packaging states that “Our packaging is made from 50% plant-based renewable materials. Because we turn fast-growing plants into bio-plastics, only half of our product is made from petroleum-based materials.” If substantiated, this claim is unlikely to be deceptive.

Example 3: Through testing, a marketer can establish that its product is composed entirely of biological material. It markets its product as “made with 100% renewable materials.” This claim, without further explanation, likely conveys that the product has other environmental benefits, including that it is recyclable, made with recycled content, or biodegradable. If the marketer cannot substantiate these messages, the claim would be deceptive.

§ 260.16 Source reduction claims.

It is deceptive to misrepresent, directly or by implication, that a product or package has been reduced or is lower in weight, volume, or toxicity. Marketers should clearly and prominently qualify source reduction claims to the extent necessary to avoid deception about the amount of the source reduction and the basis for any comparison.

Example 1: An advertiser claims that disposal of its product generates “10% less waste.” Because this claim could be a comparison to the advertiser’s immediately preceding product or to its competitors’ products, the advertiser should have substantiation for both interpretations. Otherwise, the advertiser should clarify which comparison it intends and have substantiation for that comparison. A claim of “10% less waste than our previous product” would not be deceptive if the advertiser has substantiation that shows that the current product’s disposal contributes 10% less waste by weight or volume to the solid waste stream when compared with the immediately preceding version of the product.

By direction of the Commission.

Donald S. Clark
Secretary

[FR Doc. 2010–25000 Filed 10–14–10; 8:45 am]

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Federal Register

**Friday,
October 15, 2010**

Part III

Department of the Interior

**Bureau of Ocean Energy Management,
Regulation and Enforcement**

30 CFR Part 250

**Oil and Gas and Sulphur Operations in
the Outer Continental Shelf—Safety and
Environmental Management Systems;
Final Rule**

DEPARTMENT OF THE INTERIOR**Bureau of Ocean Energy Management,
Regulation and Enforcement****30 CFR Part 250**

[Docket ID BOEM-2010-0046]

RIN 1010-AD15

**Oil and Gas and Sulphur Operations in
the Outer Continental Shelf—Safety
and Environmental Management
Systems****AGENCY:** Bureau of Ocean Energy
Management, Regulation and
Enforcement (BOEMRE), Interior.**ACTION:** Final rule.

SUMMARY: This final rule establishes a new subpart under the Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) regulations to require operators to develop and implement Safety and Environmental Management Systems (SEMS) for oil and gas and sulphur operations in the Outer Continental Shelf (OCS). This rulemaking will incorporate in its entirety and make mandatory the American Petroleum Institute's Recommended Practice 75, Development of a Safety and Environmental Management Program for Offshore Operations and Facilities, with respect to operations and activities under the jurisdiction of BOEMRE. This final rule will apply to all OCS oil and gas and sulphur operations and the facilities under BOEMRE jurisdiction including drilling, production, construction, well workover, well completion, well servicing, and DOI pipeline activities. The importance of this final rule is highlighted by the Deepwater Horizon event on April 20, 2010. Although the cause of the event is presently under investigation, it further illustrates the importance of ensuring safe operations on the OCS. BOEMRE believes that requiring operators to implement SEMS will reduce the risk and number of accidents, injuries, and spills during OCS activities.

DATES: *Effective Date:* This rule becomes effective on November 15, 2010. The incorporation by reference of the publication listed in the regulation is approved by the Director of the Federal Register as of November 15, 2010.

FOR FURTHER INFORMATION CONTACT: David Nedorostek, (703) 787-1029.

SUPPLEMENTARY INFORMATION: On May 22, 2006, the former Minerals Management Service published an Advance Notice of Proposed Rulemaking (71 FR 29277), and then on June 17, 2009, BOEMRE (formerly

MMS) published a Notice of Proposed Rulemaking in the **Federal Register** entitled "Safety and Environmental Management Systems for Outer Continental Shelf Oil and Gas Operations" (74 FR 28639). The comment period for that proposed rule closed on September 15, 2009. In response to several requests, BOEMRE issued a National Notice to Lessees and Operators (NTL No. 2009-N05) on August 12, 2009, announcing a public meeting on September 2, 2009, in New Orleans, Louisiana, to discuss the proposed rule.

Summary of the Final Rule

BOEMRE is incorporating by reference, and making mandatory, the American Petroleum Institute's Recommended Practice for Development of a Safety and Environmental Management Program for Offshore Operations and Facilities (API RP 75), Third Edition, May 2004, reaffirmed May 2008. This recommended practice, including its appendices, constitutes a complete Safety and Environmental Management System (SEMS) program. On May 22, 2006, BOEMRE published an Advance Notice of Proposed Rulemaking (ANPR) in the **Federal Register** (71 FR 29277) related to requiring a SEMS program. This was followed on June 17, 2009, by a Notice of Proposed Rulemaking (NPR).

The ANPR discussed several options for implementing a SEMS program. One of these options was a comprehensive safety and environmental management approach by addressing all elements of API RP 75. API RP 75 consists of 13 sections, one of which is a "General" section. This relates to the 12 elements identified in the ANPR and states the overall principles for the SEMS program and establishes management's general responsibilities for its success. This General element is critical to the successful implementation of the SEMS program in API RP 75, and BOEMRE is including it by incorporating by reference the entirety of API RP 75.

The NPR proposed regulatory text premised on the four critical elements of API RP 75 (hazards analysis, management of change, operating procedures, and mechanical integrity). BOEMRE noted all elements of API RP 75 in the proposed rule, stating that a SEMS program should be modeled after the requirements of API RP 75, but did not propose to incorporate all elements of API RP 75. However, several comments suggested that BOEMRE should incorporate by reference and require implementation of all elements of API RP 75. BOEMRE has determined that for the SEMS program to be most

effective, the entirety of API RP 75 needs to be included in the program and has required as much in the final rule. BOEMRE also believes that adoption of API RP 75 in its entirety is consistent with the direction of the National Technology Transfer and Advancement Act of 1996, which directs agencies, wherever possible, to adopt private standards.

This final rule will therefore require the operator (a lessee, the owner or holder of operating rights, or the designated operator) to integrate a comprehensive SEMS program into the management of their OCS operations, thereby providing for the prevention of waste and conservation of natural resources of the Outer Continental Shelf. In addition, BOEMRE is highlighting certain requirements from API RP 75 and further describing those requirements in the regulatory text to clarify compliance requirements. It is the intent of this rule to hold the operator accountable for the overall safety of the offshore facility, including ensuring that all contractors and subcontractors have safety policies and procedures in place that support the implementation of the operator's SEMS program and align with the principles of managing safety set forth in API RP 75. Nothing in this final rule shall affect the Coast Guard's authority and jurisdiction over vessels and offshore facilities. This final rule will require all elements of API RP 75 as follows:

- (1) General, with additional clarification in § 250.1909,
- (2) Safety and Environmental Information, with additional clarification in § 250.1910,
- (3) Hazards Analysis, with additional clarification in § 250.1911,
- (4) Management of Change, with additional clarification in § 250.1912,
- (5) Operating Procedures, with additional clarification in § 250.1913,
- (6) Safe Work Practices, with additional clarification in § 250.1914,
- (7) Training, with additional clarification in § 250.1915,
- (8) Assurance of Quality and Mechanical Integrity of Critical Equipment, (Mechanical Integrity), with additional clarification in § 250.1916,
- (9) Pre-startup Review, with additional clarification in § 250.1917,
- (10) Emergency Response and Control, with additional clarification in § 250.1918,
- (11) Investigation of Incidents, with additional clarification in § 250.1919,
- (12) Audit of Safety and Environmental Management Program Elements, (Auditing), with additional clarification in §§ 250.1920, 1924, and 1925, and

(13) Records and Documentation, (Recordkeeping and Documentation), with additional BOEMRE requirements in § 250.1928.

BOEMRE also carried over other provisions that were contained in the proposed rule. Therefore, in implementing a comprehensive SEMS program that incorporates all of API RP 75, the operator needs to include the following in its SEMS program:

(1) Recordkeeping and documentation regarding specification of the amount of time records are to be kept;

(2) Clarification of the differences between hazards analysis (facility level) and job safety analysis (task level);

(3) Procedures to verify that contractors are conducting their activities in accordance with the operator's SEMS program and an evaluation to ensure that contractors have the skills and knowledge to perform their assigned duties;

(4) An independent third-party or your designated and qualified personnel must conduct all SEMS audits;

(5) Audit documentation must be submitted to BOEMRE;

(6) Other documentation to be made available to BOEMRE upon request;

(7) OCS performance measures data (Form MMS-131).

The following table provides a summary of the individual provisions and their associated cost for implementation and annual maintenance of a SEMS program. No costs are identified for implementation of a SEMS program by high activity operators because all high activity operators currently have a SEMS program. Implementation costs for moderate and low activity operators that have a partial SEMS program are lower than those operators without a SEMS program.

| Elements | Implementation (moderate) | | Implementation (low) | | Maintenance (high) | Maintenance (moderate) | Maintenance (low) |
|--|---------------------------|----------------|----------------------|----------------|--------------------|------------------------|-------------------|
| | Partial | Full | Partial | Full | | | |
| General | \$18,000 | \$18,000 | \$5,000 | \$5,000 | \$50,000 | \$3,000 | \$2,000 |
| Safety and Environmental Information | 0 | 22,000 | 0 | 8,000 | 75,000 | 12,000 | 3,000 |
| Hazards Analysis | 0 | 98,000 | 0 | 23,000 | 300,000 | 34,000 | 14,000 |
| Management of Change | 0 | 29,000 | 0 | 18,000 | 150,000 | 21,000 | 7,000 |
| Operating Procedures | 0 | 20,000 | 0 | 10,000 | 100,000 | 17,000 | 4,000 |
| Safe Work Practices | 0 | 28,000 | 0 | 12,000 | 125,000 | 17,000 | 5,000 |
| Training | 0 | 30,000 | 0 | 14,000 | 200,000 | 25,000 | 9,000 |
| Mechanical Integrity | 0 | 38,000 | 0 | 19,000 | 225,000 | 27,000 | 11,000 |
| Pre-startup Review | 25,000 | 25,000 | 8,000 | 8,000 | 125,000 | 16,000 | 5,000 |
| Emergency Response and Control | 28,000 | 28,000 | 14,000 | 14,000 | 175,000 | 24,000 | 7,000 |
| Investigation of Incidents | 20,000 | 20,000 | 10,000 | 10,000 | 95,000 | 17,000 | 3,000 |
| Audits | 3,000 | 3,000 | 2,000 | 2,000 | 15,000 | 6,000 | 6,000 |
| Records and Documentation | 6,000 | 6,000 | 4,000 | 4,000 | 30,000 | 6,000 | 4,000 |
| Total | 100,000 | 365,000 | 43,000 | 147,000 | 1,665,000 | 225,000 | 80,000 |

Total One-time Implementation: \$655,000.
Total Annual Maintenance: \$1,970,000.

BOEMRE may enforce non-compliance with any of the requirements of 30 CFR part 250 subpart S, in a variety of ways. BOEMRE may issue incidents of non-compliance (INCs) following an inspection where BOEMRE determines that a facility is conducting operations that do not comply with the requirements of subpart S, or after a BOEMRE directed independent third-party SEMS audit. If BOEMRE identifies non-compliance with subpart S as a result of a regularly scheduled SEMS audit and all deficiencies discovered during the course of the audit are sent to BOEMRE with a schedule for their correction, then BOEMRE will consider this in deciding whether to issue an INC. However, if the operator does not meet its schedule of corrections, BOEMRE will be more likely to issue an INC.

If non-compliance resulting from an inspection or BOEMRE-directed audit poses actual harm or threat to the human and marine environment, BOEMRE will proceed with a civil penalty review of that violation(s) subject to 30 CFR part 250, subpart N—

Outer Continental Shelf Civil Penalties. Should non-compliance with subpart S display serious and pervasive safety management concerns, BOEMRE may restrict or revoke the operator's privilege to operate on the OCS as a designated operator or lessee operator through probationary or disqualification actions as detailed in § 250.135.

Notice of Proposed Rulemaking Comments

In response to the proposed rule, BOEMRE received 61 sets of comments, of which 57 were from individual entities (companies, industry organizations, or private citizens). Some of the 61 comments were duplicates, not related to the proposed rule, or the same company submitting multiple comments. All of the comments received are posted on the BOEMRE Web site at: <http://www.BOEMRE.gov/federalregister/PublicComments/AD15SafetyEnvMgmtSysforOCSOilGasOperations.htm>.

Multiple comments stated that they do not support the proposed rule as written because it will eliminate the

flexibility needed for any safety management system to work effectively, including flexibility inherent in the API RP 75 approach.

Five comments received recommended that BOEMRE should move forward to implement its plan to require a SEMS for oil and gas and sulphur operations on the OCS and that the proposed rule should require that offshore operators implement all elements of API RP 75. Other comments suggested various combinations of the API RP 75 elements.

The majority of the comments received stated that SEMS should remain voluntary and the proposed rule, as written, would increase documentation and recordkeeping requirements and would not address human factors (i.e., errors, behavior, etc.). Several comments recommended that BOEMRE incorporate the JSA into current 30 CFR part 250 regulations to address human factors as an alternative to incorporating the four elements.

Numerous comments received from drilling, production, and service contractors stated that BOEMRE already

has regulations in place to address employee training and competency assessments in 30 CFR part 250, subpart O—Well Control and Production Safety Training, and recommended that BOEMRE strike the section relating to contractors from the rule because it is redundant with the existing subpart O regulations.

A few comments received from industry trade organizations (API, International Association of Drilling Contractors (IADC), Offshore Operators Committee (OOC)) stated that the proposed rule as written will require lessees and operators to modify existing SEMS programs and that rewriting these programs would not prevent accidents or increase safety.

In response to the comments we address the general comments and those that pertain to several sections of the rule first. Following that, we have a section-by-section discussion of the specific comments received and our response to those comments, including any changes made to the final rule.

General Comments

Contractor Selection Criteria

Comment: Nearly every comment addressed contractor selection criteria. They stated that BOEMRE already has regulations in place (30 CFR part 250, subpart O—Well Control and Production Safety Training) that address training and competency assessment for contractors. In addition, they stated that BOEMRE was requiring contractors to have a SEMS program.

Response: We incorporated by reference API RP 75, Section 7, which addresses training. Subpart O addresses training and competency for contractors. The operator may use the training requirements in subpart O to meet part of the requirements of Section 7. As part of their SEMS program, operators must establish and implement training programs so that all personnel are trained to work safely and are aware of environmental considerations offshore, in accordance with their duties. The SEMS program must address contractor training to ensure and verify that contractors have their own written safe work practices and contractors may adopt appropriate sections of the operator's SEMS program. The operator must have a SEMS program and is responsible for obtaining and evaluating information regarding the contract employer's safety performance and safety programs to ensure that skilled, knowledgeable, and properly trained personnel are working on the OCS. In order to comply with this rule, an operator must ensure that its contractors

are conducting their operations in accordance with the operator's SEMS program. The operator must work with the contractor regarding appropriate contractor safety and environmental policies and practices before a contractor begins work at the operator's facilities.

Jurisdictional Authority

Comment: Most comments expressed concern that BOEMRE had overstepped its jurisdictional authority by imposing management safety system requirements in the proposed rule on mobile offshore drilling units (MODUs). Comments questioned BOEMRE's authority to require an operator to have a SEMS on a MODU.

Response: BOEMRE has jurisdictional authority to adopt and implement this rule. The final rule will require operators to have a SEMS for a MODU when it is under BOEMRE's jurisdiction such as during drilling, well workover, well completion, and servicing operations.

The U.S. Offshore Industry Safety Record

Comment: Most comments expressed the view that the safety and environmental protection record of the offshore industry is excellent, and that imposing these new requirements is not justified.

Response: BOEMRE disagrees that the final SEMS regulation is not justified in light of the available incident data and the trends identified through analyzing this data as discussed in the ANPR and preamble of the proposed SEMS rule. This analysis covers 10 years (from 2000 to 2009) of OCS oil and gas operations, including Incidents of Noncompliance (INCs), accident panel investigation reports, incident analysis, and OCS spill analysis. It shows that the majority of INCs and accidents during that period were related to human factors and not to equipment failure. Thus, additional regulations are needed to address how operators can reduce the risk of incidents during OCS activities.

The ANPR and the proposed rule describe numerous incidents that indicate the need for a comprehensive SEMS program. The recent Deepwater Horizon incident is a significant reminder of the risk of offshore operations and the need to regularly evaluate measures that help ensure safe operations. A SEMS program will augment existing safety requirements.

Root Cause

Comment: Most comments stated that BOEMRE's assertion that "root cause analysis" points to the need for

requiring the four proposed SEMS elements, is not supported by the BOEMRE's incident analysis.

Response: BOEMRE believes that the SEMS regulation is justified given the available incident data trends and associated analysis discussed in the ANPR and preamble of the proposed and final SEMS rule. As mentioned previously, the analysis covered over 10 years and demonstrates that requiring operators to implement a SEMS program is likely to improve OCS safety. BOEMRE incident analysis supports adopting all 13 elements. Voluntary data submitted by industry should not be construed as BOEMRE data as it is incomplete and unverified. BOEMRE data is the only source of industry-wide data available.

Job Safety Analysis/Job Hazards Analysis

Comment: Most comments claimed that the job safety analysis/job hazards analysis is the only significant portion of the proposed rule that could affect the behavioral issues related to an incident.

Response: BOEMRE agrees that a JSA/JHA does address behavioral change with the goal of minimizing accidents, but disagrees that it is the only portion of the rule that bears on behavior. In the final rule, BOEMRE is incorporating all elements of API RP 75, much of which addresses behavioral issues and additional regulatory requirements to clarify expectations for compliance.

Mandated SEMS Program

Comment: Most comments strongly disagree that a mandated SEMS program as proposed is needed. The comments stated that a mandated program will not reduce OCS incidents any more than a voluntary SEMS program. As such, they recommend BOEMRE keep SEMS voluntary.

Response: BOEMRE disagrees. In 1998, operators accounting for 98 percent of OCS production reported that they were covered under a SEMS. By 2006, this number decreased to approximately 60 percent (see API RP 75 implementation survey at: <http://www.BOEMRE.gov/sempr/Reports/survey98.htm>). A voluntary SEMS program has not been adopted by all operators. The only way to ensure the adoption of a SEMS program by all operators is to require that all operators implement such a program.

Comment: The other option proposed by some comments was to mandate a program for those operators who have a historical record of poor performance.

Response: BOEMRE does not agree that this is the most effective approach.

The purpose of requiring a SEMS program is to reduce the risk and number of incidents during OCS activities, which is not solely based or determined by an operator's past record of poor performance.

Withdraw Proposed Rule

Comment: Many comments stated that BOEMRE should withdraw the proposed rule immediately and reevaluate the cost/benefits of mandating a program that, as recently as 2003, was determined by the agency to be performing well as a voluntary program.

Response: BOEMRE disagrees. The only way to ensure SEMS programs are used across the entire OCS is to require a program for all operators. As of 2009, only 54 percent of OCS operators had a SEMS program, and not all of the 54 percent include the entirety of APR RP 75 in their SEMS program.

Underestimated Cost

Comment: Most comments expressed that BOEMRE significantly underestimated the cost of developing, revising, and implementing the SEMS program. Comments also stated that BOEMRE dramatically underestimated the major new documentation and reporting burden that the rule will impose on offshore operators.

Response: BOEMRE re-evaluated the cost burden on industry by interviewing parties experienced in the development of SEMS programs, vendors that submit information for operators, and operators with designated personnel who work on SEMS issues. Based on this information, we have increased the non-hour cost and hour burdens. Should OCS companies have documented data that shows a higher cost to industry, they may submit comments at any time on the paperwork burden as stated in § 250.199(d).

New Reporting, Documentation, and Recordkeeping Requirements

Comment: Several comments claim that this proposed rule attempts to prescribe new reporting, documentation, and recordkeeping requirements far above current levels in API RP 75, that will adversely impact OCS operators' businesses, both operationally and financially, while bringing little benefit towards improving safety of offshore operations.

Response: BOEMRE changed the reporting and recordkeeping requirements from the proposed rule to the final rule. We are now incorporating all elements of API RP 75, with requirements in § 250.1928 to enhance documentation and recordkeeping. The

reporting and recordkeeping requirements in this final rule are primarily submissions of documents that are directed by the adoption of API RP 75 and used to comply with this recommended practice. The reporting to BOEMRE is necessary to ensure the bureau has the appropriate documentation to monitor compliance with this rule.

Comment: The operator can only supply the information on the Form MMS-131 by collecting and consolidating information from their contractors, suppliers, and vendors and, in turn, any subcontractors or other workers involved in OCS operations. This is not a current practice and it will require a significant amount of time to establish and maintain a reporting system. Further complications will arise since a significant portion of work may be contracted out as "lump sum" turnkey projects where individual worker hours are not provided to the operator.

Response: Such information is critical to the effective implementation of a SEMS program. While operators may not currently require contractors, suppliers, and vendors to submit this information, it is not unreasonable to expect them to provide it to the operator. Regarding "lump sum" turnkey projects, individual worker hours could be estimated as a normal practice. For example, a contractor may have workers who stay offshore for 2 weeks at a time and work 12 hour shifts. Therefore, a crew of 20 people, could be estimated to work a total of 240 hours per day for 14 continuous days (240 hours × 14 days = 3,360 hours).

Comment: While most contractors on the OCS probably collect information regarding employee work hours and injuries/illnesses for their own use, they typically do so either on a quarterly or annual basis, not the per-contract basis which would be necessitated by the proposed action.

Response: Operators will need to work with their contractors to establish the best approach to provide the information required by this rule.

Comment: Collection and reporting of information that only becomes available post-contract is problematic. For example: Will the operator be expected to report days of continuing restricted work activity for a contractor's employee injured while working for the operator after the termination of the contract?

Response: Once the contract has been terminated, the contractor's employee is no longer working for the operating company in question. Form MMS-131 only requests that an operating company

provide information for contractors under their employment during the calendar year. Operating companies will only be required to provide information tallied for the portion of the year the contractor is under the operating company's employment, not for the entire year.

Comment: There is no consistent industry practice of collecting information regarding work hours and injuries/illnesses from sub-contractors and other (possibly occasional) workers. The proposed action would require the establishment of such an information collection and reporting system. The collection of such information regarding occasional workers (e.g., equipment repair specialists), particularly those providing services on a per-job (rather than hourly) basis will be particularly challenging.

Response: In § 250.1914(e)(2), BOEMRE requires the operator to keep an injury/illness log, retain it for 2 years, and include this information on Form MMS-131. The operating company is responsible for collecting and submitting this data and will need to work with their contractors to establish a process for doing so.

Comment: BOEMRE has not, with this proposed version of Form MMS-131, provided the necessary instructions and definitions for the user to understand the information collection and comply with the reporting requirement. The instructions and definitions should be made available, with the proposed form, for public comment. The information collection should not be authorized until clear and unambiguous instructions are provided.

Response: There is no need to make proposed Form MMS-131 available for public comment since it was previously made available for comment in the proposed rule. However, in light of your comment concerning the instructions, the BOEMRE is providing explicit instructions to guide respondents on completing the form. See Appendix 1 of the final rule.

Comment: Cost and time estimates are more in line with the printing of manuals and instructions and not actual or historical costs we have as operators experienced for the development, implementation, and long term support of a new program.

Response: BOEMRE re-evaluated the cost burden on industry by interviewing parties experienced in the development of SEMS programs, vendors that submit information for operators, and operators with designated personnel who work on SEMS issues. Based on this information, we have increased the non-hour cost and hour burdens. If OCS companies

have documented data that shows a higher cost to industry, they may submit comments at any time on the paperwork burden as stated in § 250.199(d).

Comment: The proposed rule does not take into consideration the impact that the requirements and administrative burden will force on small independent contractors and service suppliers who perform a large portion of the field work typically carried out on OCS facilities.

Response: The operators must submit Form MMS-131 to BOEMRE, not small independent contractors and service suppliers. BOEMRE foresees that the primary impact for these groups is that they are now expected to provide information on the man-hours. That task may be as simple as taking note of the time specific employees report in and out of a specific work site and tracking that data. Operators will need to work with their contractors to establish the best approach to provide the information required by this rule.

Comment: We ask that BOEMRE appropriately acknowledge the entire burden being imposed by this rulemaking on the industry and account for it within its information collection budget.

Response: This is discussed in more detail in the Procedural Matters of this rulemaking under the Regulatory Flexibility Act and Paperwork Reduction Act section. If OCS companies have documented data that shows a higher paperwork burden than what BOEMRE estimates, they may submit comments at any time on the paperwork burden as stated in § 250.199(d).

Unnecessary Burden on BOEMRE

Comment: Most comments claim that implementing this proposed rule will create an additional burden to regional BOEMRE staff that will require additional inspector/auditor training and increased workloads.

Response: While this is additional work, we consider this regulation critical to improve safety on the OCS. BOEMRE will adjust inspector training and workload as necessary to ensure effective implementation of the rule.

Where BOEMRE Believes the Industry Is Falling Short of Expectations

Comment: Several comments would like to know specifically where BOEMRE believes the industry is falling short of BOEMRE's expectations regarding safety and why the BOEMRE has not shared this information in the rulemaking.

Response: The proposed rule was developed based upon 33 accident panel investigations, 1,443 incident

analyses, and 3,132 INCs issued by the agency. Additional information about these items is publicly available at: <http://www.BOEMRE.gov/incidents/index.htm> and http://www.gomr.BOEMRE.gov/homepg/offshore/safety/acc_repo/accindex.html.

For the SEMS program to be most effective, the entirety of API RP 75 needs to be part of the program, which the final rule requires.

Remove Prescriptive Language

Comment: A few comments pointed out that if BOEMRE intends to require that each SEMS conform to API RP 75, then the highly prescriptive language should be removed and the final rule should simply reference the appropriate sections in API RP 75. They recommend that BOEMRE incorporate by reference API RP 75 into the regulations and require compliance with the existing recommended practice. In addition, the comments state that the proposed rule, as written, not only represents an abrupt change from past direction of the BOEMRE, but it also penalizes those operators that took the initiative and developed programs patterned after the API RP 75 model. For operators that implement API RP 75 and continue to evolve their systems to keep abreast of changing operations, having the BOEMRE implement a 4 element SEMS will require them to go back and modify or change those systems to comply with new BOEMRE prescriptive requirements. These changes to programs that are working effectively will add minimal if any added value.

Response: The final rule incorporates, and thus prescribes, all of API RP 75, as well as requirements as detailed in 30 CFR 250 subpart S for recordkeeping and documentation, JSAs for activities identified in the SEMS programs, contractor selection criteria, and audit requirements.

Implementation

Comment: A commenter pointed out that the rule calls for the program to be implemented within 1 year after the final rule becomes effective. For operators that do not already have a written SEMS program that covers all of the elements, it will be impossible to develop the SEMS program, conduct all of the hazards analyses (facility), complete job hazards analysis for every job, write complete operating procedures, establish a mechanical integrity program, and establish an audit program for everyone on their facilities. Even for those operators that have a SEMS in place, it is likely to take more than 1 year to compare their existing program to the prescriptive

requirements in this rulemaking and make all of the required modifications. Therefore, if a mandatory program is adopted, the commenter recommends that a phased-in approach to implementation be adopted.

Response: BOEMRE believes that 1 year is a sufficient amount of time for operators to develop their SEMS program, even if they do not already have a program in place. The final rule incorporates by reference, and thus prescribes, the entirety of API RP 75 together with related requirements for recordkeeping and documentation, JSAs for activities identified in the SEMS programs, and contractor selection criteria. BOEMRE believes that 1 year is a sufficient amount of time for operators to put these related requirements of the program in place.

Three Alternatives for Consideration

Comment: A comment suggested that in lieu of pursuing the rulemaking in its current form, the BOEMRE should consider the following three alternatives:

1. Suspend the rulemaking and continue with the voluntary program currently in place.
2. Suspend the rulemaking and return to the Advance Notice of Proposed Rulemaking.
3. Abandon the concept of a new prescriptive section in the regulation and simply include the following language in § 250.107:

(e) You must have a safety and environmental management program in accordance with the American Petroleum Institute's Recommended Practice for Development of a Safety and Environmental Management Program for Offshore Operations and Facilities (API RP 75), incorporated by reference as specified in § 250.198.

(1) At a minimum, your safety and environmental management program must include:

(i) Hazards Analysis. You must perform a hazards analysis for all OCS facilities to identify, evaluate, and, where unacceptable, reduce the likelihood and minimize the consequences of uncontrolled releases and other safety or environmental incidents. This includes having a job safety analysis process. Human factors should be considered in this analysis,

(ii) Management of Change. You must establish procedures to identify and control hazards associated with change and maintain the accuracy of safety information,

(iii) Operating Procedures. You must have written facility operating procedures designed to enhance

efficient, safe, and environmentally sound operations,

(iv) Mechanical Integrity. You must ensure that procedures are in place and implemented so that critical equipment for any facility subject to this recommended practice is designed, fabricated, installed, tested, inspected, monitored, and maintained in a manner consistent with appropriate service requirements, manufacturer's recommendations, BOEMRE requirements, or industry standards, and

(v) Documentation. You must establish a documentation system to ensure that records and documents are maintained in a manner sufficient to implement your safety and environmental management program. Records or documentation may be in either paper or electronic form. You must make this documentation available for BOEMRE inspection upon request.

* * *

Response: BOEMRE disagrees with all three of the proposed alternatives. Not all operators on the OCS voluntarily submit Form MMS-131. A comprehensive SEMS program is important. The final rule incorporates, and thus prescribes, API RP 75, and requirements for recordkeeping and documentation necessary to implement API RP 75, JSAs for activities identified in the SEMS programs, contractor selection criteria and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf.

Potential Adverse Impacts to Drilling Contractors

Comment: A commenter expressed concern that any prescriptive imposition of mandatory SEMS elements upon operators has the potential to adversely impact drilling contractors' SEMS, if a careful balance between the operators' perceived need to impose those SEMS elements against the contractors' need to manage their own SEMS is not achieved. Clearly the goal should be that a drilling contractor should move between operators with little, if any, modification to the contractor's SEMS.

Response: The final rule does not require that a contractor have a SEMS program. The final rule requires operators to ensure that contractors have their own written safe work practices and provides that they may adopt appropriate sections of the operator's SEMS program. The operator must have a SEMS program and is responsible for obtaining and evaluating information regarding the contractor's safety

performance and programs. An operator and contractor should agree on appropriate contractor's safety and environmental policies and practices before the contractor begins work at the operator's facilities.

BOEMRE Meetings With Industry

Comment: Several comments state that BOEMRE should have held meetings with industry so that industry comments and views could have been placed on the record. An informal "workshop" without public recording of industry views is insufficient to reflect the depth of concern held by exploration and production companies operating on the OCS and the numerous other companies that support their activities. Even though BOEMRE held a public meeting in September 2009, it did not have official recording of comments.

Response: BOEMRE disagrees. BOEMRE has publicized its views that a SEMS rule is needed since 1993 at a variety of industry conferences and meetings. At these meetings, BOEMRE explained that the agency supported implementation of a comprehensive SEMS program. These meetings presented the industry with numerous opportunities for dialog with BOEMRE regarding this type of program. In 1994, API RP 75 was developed with input from industry. In addition, the BOEMRE published its views in an ANPR in 2006, which discussed BOEMRE's consideration of a comprehensive API RP 75-based program, and an NPR in 2009. At the September 2009 meeting, attendees were encouraged to submit written comments.

Rule Lacks Specifics

Comment: Several comments stated that the proposed rule lacks specificity in some areas, as well as in the discussion on hazard/safety analyses. It is the commenters' concern that without specifics, there will be inconsistency with regard to interpretation, which will be difficult on the industry, as well as BOEMRE, to implement and enforce.

Response: The final rule incorporates, at an appropriate level of detail, requirements necessary for recordkeeping and documentation to implement API RP 75, JSAs for activities identified in the SEMS programs, contractor selection criteria and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf.

Agency Jurisdiction

Comment: Several comments stated that it is not clear that BOEMRE is

expanding its reach into other agencies' jurisdiction, and do not understand how this will help safety. BOEMRE's proposal to handle enforcement issues on MODUs, where the USCG has jurisdiction and has done a very good job over the years with their limited resources, is a duplication of efforts and a power grab by BOEMRE. Requiring mandatory reporting to BOEMRE when Occupational Safety and Health Administration (OSHA) is the appropriate agency is another area of duplication and another power grab by BOEMRE. The comments stated that they may be misreading the information, but it also appeared that BOEMRE is attempting to take over jurisdiction of Department of Transportation (DOT) regulated pipelines. If this is the case, here is another attempt at duplication or a power grab by BOEMRE.

Response: BOEMRE disagrees. A SEMS will and should apply to MODUs when they are under BOEMRE's jurisdiction (*i.e.*, drilling, well workover, well completion, servicing operations). The final rule clarifies that the SEMS program must address DOI regulated pipelines only. BOEMRE, DOT, and USCG establish the requirements for workplace safety on the OCS with requirements that pertain to personal protection equipment, tripping and slipping hazards, deck openings, means of escape, fire extinguishers, and other workplace safety items. The OSHA requirements do not apply to OCS operations.

Support for the Proposed Rule

Comment: Some comments supported BOEMRE in requiring OCS oil and gas operators to implement SEMS rules, which are intended to reduce human error and organizational failures. The analysis summarized in the proposed rule indicates that the elements are associated with contributing causes of most incidents, hence the rationale for focusing on them. Comments requested that this regulation require, rather than simply encourage, that offshore operators implement all elements of the API RP 75, as identified in the rulemaking notice.

Response: Upon review of all the comments and the requirements of API RP 75, BOEMRE agrees that a SEMS program should be comprehensive to reduce human error and organizational failures. Therefore, BOEMRE incorporated all elements of API RP 75 with requirements necessary to implement API RP 75 and regulatory language to clarify expectations for compliance.

Comment Period

Comment: The comment period to such a significant, formal rule, was not long enough and it is recommended that further discussions with industry be carried out prior to any final rulemaking.

Response: BOEMRE disagrees. BOEMRE published an ANPR in 2006 notifying industry that we were considering requiring a comprehensive SEMS program and seeking comment. The proposed rule was published on June 17, 2009, with a 90-day comment period. BOEMRE also held a workshop on September 2, 2009 at which attendees were encouraged to submit written comments on the proposed rule. This comment period is consistent with comment periods for other rules of this magnitude. Thus, sufficient response time was afforded for interested parties to submit comments.

General Comments

Comment: A SEMS approach is more applicable to production facilities; MODU, liftboat, and coiled tubing operations are inherently more hazardous than production facility operations, and lead to more well control incidents.

Response: BOEMRE believes that SEMS has merit for all OCS operations including, but not limited to, production, drilling, well completion, well workover, well servicing, and coiled tubing. For SEMS to be properly implemented, it needs to address all OCS operations. Liftboats are under the jurisdiction of the USCG and are not covered by this regulation.

Comment: Support a more focused SEMS program for production facility management (excluding MODU operations), preferably one that is voluntary. Such a program, with elements of hazards analysis and management of change, probably could be helpful especially for smaller operators.

Response: BOEMRE disagrees. A SEMS should apply to MODUs and all other facilities under BOEMRE's jurisdiction. The final rule will require operators to have a SEMS for operations and activities onboard a MODU when it is under BOEMRE's jurisdiction such as drilling, well workover, well completion, and servicing operations.

Comment: Does the definition of facility in this section apply to all the sections in subpart S?

Response: BOEMRE is incorporating by reference API RP 75, including the definitions from Appendix D of API RP 75, except as revised in the final rule.

Comment: How does BOEMRE perceive the difference between a Job

Hazards Analysis (JHA) and a Job Safety Analysis (JSA)?

Response: A JSA is one form of hazards analysis. Hazards analysis is performed to identify and evaluate hazards for the purpose of their elimination or control. A JSA is a process used to review site-specific detailed job steps and uncover hazards associated with the specific job undertaken. To alleviate any confusion, BOEMRE replaced the term JHA with JSA in the final rule.

Comment: Is the JHA for each general operation or for the immediate task at hand?

Response: BOEMRE removed the term JHA from the final rule. In the final rulemaking, JSAs are required for the immediate tasks at hand and are not required for general operations.

Comment: What is BOEMRE's expectation for what triggers an internal audit and updating a facility hazards analysis?

Response: The final rule requires operators to have their SEMS program audited by either an independent third party or your designated and qualified personnel, according to the requirements of this subpart and API RP 75, Section 12. The first audit must be within 2 years of the initial implementation of the SEMS program and at least once every 3 years thereafter. However, BOEMRE may issue additional guidance on this after the final rule is implemented. BOEMRE may direct specific operators to conduct additional independent third-party audits or BOEMRE may conduct an audit, if we identify safety or non-compliance concerns based on the results of inspections and evaluations, or as a result of an event.

The operator must update the appropriate elements of their SEMS program, if there are deficiencies identified in the audit. For updating a hazards analysis for a facility, we incorporated by reference the requirements of API RP 75, Section 4.4, which requires that if a management of change is conducted due to changes in personnel, facility and operating conditions, then the operator must conduct a hazard analysis on those changes. For simple and nearly identical facilities, such as well jackets and single well caissons, the operator may use the same single hazards analysis after verifying that any site-specific deviations have been identified and addressed (*see* § 250.1911).

Comment: Recommend in proposed section § 250.1907 "What criteria for Mechanical Integrity must my SEMS program meet?" that "manufacturer's recommended limits" should be

changed to manufacturers and/or engineering design limits.

Response: We disagree; we believe that the manufacturers recommended limits are the most appropriate guidance to use.

Comment: What are BOEMRE's definitions of temporary operations, personnel change, and facility?

Response: See the scope of "facilities" addressed in § 250.1911 and Appendix D of API RP 75, incorporated by reference, which includes a definition of "facility." As to personnel change, we are now incorporating by reference API RP 75, Section 4, which defines "personnel change" in Section 4.3. The term "temporary operations" was removed from the final rule. It is the operator's responsibility to ensure all contractors subscribe to basic safety workplace principles that meet the spirit and intent of the operator's SEMS program.

Comment: Does BOEMRE support API RP 75 guidance on MOC as being sufficient to direct operators in developing an effective MOC process?

Response: The guidance provided in API RP 75, Section 4, which we incorporated by reference in the final rule, along with the requirement in § 250.1912 of the final rule provides sufficient guidelines and procedures on when and how to develop a MOC process.

Comment: How does BOEMRE perceive the difference between documenting the inspection and tests that have been performed, and verification that inspections and tests are being performed?

Response: BOEMRE will evaluate all of the documentation provided to verify that the inspections and tests were performed and that the operator continues to perform the inspections and tests, as described in their SEMS. BOEMRE is vigilant about operator documentation and may use a variety of tools to determine the validity of operator records and that the operator is conducting all prescribed and appropriate tests, as identified in their SEMS.

Comment: Are there contractor groups that BOEMRE believes are not being addressed by existing subpart O requirements—identify. We believe this is redundant with the existing subpart O program.

Response: BOEMRE does not regulate contractors; we regulate operators. Subpart O applies to well control and production safety, whereas this SEMS final rule applies to operators who are performing or who have contractors performing maintenance or repair, turnaround, major renovation, or

specialty work on or adjacent to a covered process. The training requirements of subpart O may be used to partially meet the SEMS requirements.

Comment: Can you provide detailed instructions and examples for filling out Form MMS-131?

Response: The form and instructions are in Appendix 1 which is incorporated by reference into the rule and is also set forth in the preamble of the final rule.

Comment: BOEMRE fails to recognize that our voluntary safety and environmental programs are effective.

Response: The voluntary programs may be effective for those who follow the guidance completely. However, more needs to be done to promote safety of the environment and the personnel working on the OCS by ensuring that everyone complies with API RP 75 and the requirements of this final rule.

Comment: BOEMRE fails to understand that our safety record is good and is only getting better.

Response: The record of incidents that cause injuries, fatalities, fires, collisions, loss of well control, or explosions demonstrates the need for regular evaluation and improvement of safety standards.

Comment: BOEMRE fails to understand that the prescriptive SEMS program will not address many of the incidents/accidents that the regulation is based on.

Response: BOEMRE does not agree that the voluntary program has been as effective as it could be. Industry wide adoption of SEMS is crucial to enhancing safety in the OCS.

Comment: BOEMRE wrote prescriptive requirements for all or part of 8 of the 12 SEMS elements in lieu of just following API RP 75.

Response: BOEMRE is incorporating all elements of API RP 75 in the final rule, with clarification of the proposed rule's requirements for JSA, recordkeeping and documentation requirements, contractor selection criteria, and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf.

Comment: The proposed rule changes the wording and expands on API RP 75, Section 5, dealing with environmental and occupation safety and health considerations. These requirements overlap with hazardous materials regulations, OPA 90, RCRA, NPDES, etc. How does BOEMRE think the addition of these requirements will impact safety performance more than the existing regulations of other agencies?

Response: SEMS is a safety management system that will enhance the effectiveness of other laws and regulations.

Comment: BOEMRE should use an alternative compliance approach, i.e., those operator/lessees that have established Safety and Environmental Management Program (SEMP) (identified by BOEMRE as 56 percent or 73 of the 130 operators) and are within the BOEMRE standard of compliance as recognized in the annual Safe Award program that would be exempt from the proposed rule.

Response: We believe that there are varying degrees of commitment and compliance with the voluntary SEMP program and that a mandatory program is the best way to ensure that operators implement a comprehensive approach to safety. Operators that have a comprehensive SEMS program in place addressing all of API RP 75 are already addressing many of the requirements in this final rule.

Comment: Some operators have existing processes that address changes. Consideration should be given to these existing processes and not develop a prescribed MOC process for changes that are already covered.

Response: BOEMRE changed the final rule by incorporating by reference API RP 75, Section 4, to address MOCs. You may use your existing MOC process if it meets the requirements of API RP 75 and § 250.1912.

Comment: We believe that the one size fits all approach to this rule does not take into account the diversity of operations that exists in the OCS.

Response: SEMS is not a one size fits all program. In fact, SEMS encourages operators to consider unique circumstances and conditions. BOEMRE changed the final rule by incorporating all elements of API RP 75 and requirements for recordkeeping and documentation necessary to implement API RP 75, JSAs for activities identified in the SEMS programs, contractor selection criteria, and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf to allow for the diversity of operations that exists on the OCS and within the company/operation.

Comment: Please clarify if the parts of the proposed elements can be accomplished through other management systems; in other words, a comprehensive SEMS program can cover each of the proposed items without these necessarily being part of a single system.

Response: In the final rule, we are requiring all operators to follow the

elements of API RP 75 and requirements for recordkeeping and documentation, JSAs for activities identified in the SEMS programs, contractor selection criteria, and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf. As recognized in API RP 75, Section 1.3.1.1, some systems may have been developed using other guidelines. If a system was developed using other guidelines, when that system is assessed, the operator should focus on assuring that all the program elements from API RP 75 and this final rule are addressed.

Comment: What data will be made available to the public? What measures will be in place to protect sensitive company data from being made public?

Response: BOEMRE requires a copy of Form MMS-131 from an operator. The information on the Form MMS-131 is not protected from disclosure and is subject to the Freedom of Information Act (FOIA), should a member of the public request this information. BOEMRE may request a copy of the operator's SEMS and audits. BOEMRE will protect proprietary information under the Freedom of Information Act (5 U.S.C. 522) and its implementing regulations (43 CFR part 2); and 30 CFR 250.197.

Comment: We further believe that the record retention requirements for the JSA and related index are unduly burdensome and contrary to BOEMRE's stated intent that the programs not become a paperwork exercise. The proposed rule also creates concern regarding "ownership" of the JSA/index once a MODU is no longer under contract for the operator under whose contract they were developed.

Response: The retention in the final rule for the JSAs is now 30 days on-site and up to 2 years at a location of the operator's discretion. The JSA/index has been removed.

Comment: A commenter believes that BOEMRE should have a separate section in the rulemaking that pertains only to hazards analysis for MODUs.

Response: BOEMRE disagrees; the final rulemaking does not need a separate section for hazards analysis for MODUs. We incorporated by reference API RP 75, Section 3, for hazards analysis requirements, with requirements necessary to implement API RP 75 in § 250.1901 and § 250.1911.

Comment: How do we overcome human error?

Response: The intent of this rule is to reduce human error by focusing on a comprehensive SEMS program and JSAs. One result of an effectively

implemented SEMS will be to reduce human error.

Comment: If BOEMRE intends to require that each SEMS conform to API RP 75, then the highly prescriptive language should be removed and the final rule should simply reference the appropriate sections in API RP 75. Any exception or additions could be listed, similar to the approach taken in § 250.804.

Response: BOEMRE is incorporating by reference API RP 75 and requirements for recordkeeping and documentation necessary to implement API RP 75, JSAs for activities identified in the SEMS programs, contractor selection criteria and the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf.

Comment: The rulemaking is confusing with respect to the 4 types of contractor requirements, e.g., MODUs; contractors brought onto platforms for

painting/cleaning, etc.; contract operating companies; individuals working side by side with employees under head company rules. The word “employee” needs to be clarified—just the operator’s actual employees or whom?

Response: We are replacing “employees” with “personnel” and defining “personnel” in § 250.1903 in the final rule. The term “Personnel” means direct employee(s) of the operator and contracted workers who are involved with or affected by specific jobs or tasks. All personnel involved with or affected by a SEMS specific task must be trained by skilled and knowledgeable personnel to perform their assigned duties.

Comment: A comment expressed the concern that we are accepting duplicated work that is already required by DOT, OSHA, and USCG—killing trees with all the paperwork submissions.

Response: A number of federal agencies, including DOT, USCG, and BOEMRE have various responsibilities and authorities under a variety of statutes related to OCS matters. BOEMRE is not asking for duplication of paperwork that is already submitted to another government agency. Most of the information may be submitted electronically.

Section-by-Section Discussion

The industry trade organizations (Offshore Operators Committee, American Petroleum Institute, International Association of Drilling Contractors) and OCS operators submitted extensive lists of specific comments for most sections of the proposed rule. We responded to those comments in the “General Comments” section. The following table addresses more specific comments not already addressed.

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|---|---|
| 250.1903(b) | Note that, at § 250.1903(b), BOEMRE holds up ISO 14001 as an example of other standards or guidelines that meet or exceed API RP 75, seemingly encouraging such an approach as ours. However, a certified, active ISO 14001 program will not comply with the proposed regulation. | As recognized in API RP 75, Section 1.3.1.1, some systems may have been developed using other guidelines. If an operator has already developed a system using other guidelines, when the system is assessed, the focus should be on assuring that the necessary program elements from API RP 75 and the requirements necessary to implement API RP 75 in this final rule are addressed. |
| 250.1905 | Do DOI pipelines require separate hazards analyses, or is it acceptable to combine with the facility with which it is associated? | It is up to the operator to decide to combine or do a separate hazard analysis for the DOI pipelines and associated facility. However, the analysis must comply with the API RP 75 and the requirements necessary to implement API RP 75 in this final rule. |
| 250.1905 | The regulated community has varying degrees of understanding of the terms JHA and JSA. The JSAs are typically viewed as a tool to perform the OSHA required JHA. Does BOEMRE consider these terms the same? If not, please explain the difference from your understanding. The regulated community commonly understands JHA to be a broad analysis of the hazards for an overall operating procedure. A JSA is a review of a specific task at hand where the steps and hazards associated with a specific task are reviewed. To effect behavior change, we believe that a JSA is the more effective methodology than a JHA. However, it is not clear in the rulemaking which methodology BOEMRE is mandating. We note that BOEMRE Safety Alerts 276 and 282 have good descriptions of the difference between JHA and JSA. Recommendation: Please state the correlation to the appropriate section within API RP 75 such as “You must develop and implement a hazards analysis (facility level) as described in Section 3 of API RP 75.” For clarity, we recommend that job hazards analysis be changed to job safety analysis in all places in the regulation. | The terms JSA and JHA are different; therefore, in this final rulemaking we will require only JSAs. We have defined JSA in the general comments section of the preamble. |
| 250.1905 | MODU, coiled tubing, and liftboat operations are contracted. Subpart O already requires operators to verify well-control certification of contractor employees. Few operators possess specialized knowledge that would trump the certification of contractor employees. | BOEMRE agrees with this comment pertaining to the current Subpart O regulation, in part. The operator is the responsible party for all well control activities and operations, whether or not using contract personnel. If contractors are used, the operator is responsible for verifying that its contractors have the skills and knowledge to perform these operations in a safe manner. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|---|--|
| 250.1905 | <p>If a company contracts a MODU, the contractor would have to provide and support its own hazards analyses (and SEMS program) vs. the operator for which it is working. The MODUs should not be included in the list of facilities covered by this rule. The MODU operator should have a mechanical integrity and JSA program to cover operations on the rig.</p> | <p>BOEMRE disagrees. The operator must have a SEMS program. BOEMRE's intent is to have a hazards analysis as detailed in API RP 75, Section 3 and the requirements in §205.1911 of this final rule, of any MODU under BOEMRE's jurisdiction. The MODUs are considered facilities when they are used for exploration, development, production, and transportation activities for oil and gas and sulphur from areas leased in the OCS.</p> |
| 250.1905 | <p>We do not understand the reference to internal audit and know of no facility specific audits that are required. We noted that proposed §250.1910 refers to a SEMS audit, but that is on the overall program. Periodic analyses should be conducted as described in Section 3.4 of API RP 75. Does this mean hazards analyses must be updated (or revalidated) every 3 years in conjunction with the SEMS Audit? API RP 75 allows hazards analysis updates to be made at 5–10 year intervals based on risk.</p> | <p>We are incorporating by reference API RP 75, Section 3, which includes periodic analysis, to update the hazards analysis for compliance. You must update your hazards analysis as appropriate with typical review periods. The final rule requires the first audit within 2 years of implementation of the SEMS program and every 3 years thereafter, however, BOEMRE may require additional independent third party audits or BOEMRE may conduct our own audits based on poor operator performance or accidents.</p> |
| 250.1905 | <p>Recommendation: Change the last sentence to: The hazards analyses (facility level) must be reviewed periodically and updated as appropriate when changes are warranted to verify that it is consistent with the current operations on the facility, consistent with the requirements in Section 3.4 of API RP 75.</p> | <p>The operator is responsible for deciding where to keep the hazards analysis for the life of the facility. BOEMRE is removing the requirement to maintain a hazards analysis on a facility. The JHAs were removed from the final rule and replaced with JSAs. The JSAs must be retained for 30 days on the facility for BOEMRE inspection and must be made available to BOEMRE upon request for 2 years. You must maintain a copy of all SEMS program documents at an onshore location for 6 years.</p> |
| 250.1905 | <p>We see no purpose in maintaining the hazards analysis on the facility. In many cases, the facility may be an unmanned facility with no storage capability. Does BOEMRE really expect a MODU to store a hazards analysis onboard the MODU from each and every operator who has performed such an analysis? As in API RP 75, the hazard report (facility level) should be kept on file for the life of the facility. It is most appropriate that this file be kept in the operator's office where design and other facility related information is kept since this data will need to be referred to in conjunction with the hazards analysis. For job hazards analysis (commonly referred to as Job Safety Analysis-JSA), this should be kept where it is readily accessible to the personnel actually reviewing the analysis prior to performing the job it covers.</p> | <p>BOEMRE disagrees with the recommendation. Please see previous response.</p> |
| 250.1905 | <p>Recommendation: The requirement for documentation should be changed to the following: You must document and maintain current analyses for each operation covered by this section for the life of the operation. Hazards analysis (facility level) should be retained in the operator's records where the facility design information is located. The JHA (operations/task level) should be kept in a location where it is readily accessible to personnel for review prior to conducting the operation or task the analysis covers.</p> | <p>This specific reference to "property damage" is not in the final rule. BOEMRE is incorporating by reference API RP 75, which speaks to this issue.</p> |
| 250.1905 | <p>We suggest deleting "property damage" from the potential consequences included in the purpose of the facility level hazards analysis in §250.1905. The philosophy adopted with respect to property damage, also referred to as "asset protection" should be at the operator's discretion, provided that the property damage does not subsequently lead to worker injuries, fatalities, or coastal or marine environmental impacts.</p> | <p>The final rule requires the operator to ensure the development and implementation of a hazards analysis in accordance with API RP 75 and to perform a JSA at the task level in accordance with §250.1911. These must be included in the SEMS program. In order to comply with this rule, an operator and its contractors need to agree on appropriate contractor safety and environmental policies and practices before a contractor begins work at the operator's facilities.</p> |
| 250.1905 | <p>We recommend the language in §250.1905 be modified to state "You must ensure a hazards analysis (facility level) and a JHA (operations/task level) is developed and implemented for all your facilities" rather than "You must develop." The reason for this recommendation is that since MODUs are included as facilities in this subpart, it will then be clear that operators are only responsible to ensure the third-party contractors have performed a hazards analysis prior to conducting operations on the operator's lease.</p> | <p>The final rule requires the operator to ensure the development and implementation of a hazards analysis in accordance with API RP 75 and to perform a JSA at the task level in accordance with §250.1911. These must be included in the SEMS program. In order to comply with this rule, an operator and its contractors need to agree on appropriate contractor safety and environmental policies and practices before a contractor begins work at the operator's facilities.</p> |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|--------------------------|---|---|
| 250.1905 | Production contractor can have a Lockout/Tagout (LOTO) Standard that outlines the general guidelines on how to perform proper LOTO; but to generate a Hazard Assessment of a facility, the contractor would need to have access to the drawings and/or facility to address site specific equipment and issues. In some cases, contractors merely provide a resource. This resource is supervised by the client onsite. | The operator must develop and implement a hazards analysis for all of their operations in accordance with the Section 3, Hazards Analysis and §250.1911. In order to comply with this rule, an operator and its contractors need to agree on appropriate contractor safety and environmental policies and practices before a contractor begins work at the operator's facilities. |
| 250.1905 | We urge BOEMRE to revise §250.1905 to make clear that drilling vessels or utility vessels are not required to be managed under our SEMS. | BOEMRE disagrees. When a drilling vessel is under BOEMRE's jurisdiction, it is the operator's responsibility to have a SEMS program. In order to comply with this rule, an operator and its contractors need to agree on appropriate contractor safety and environmental policies and practices before a contractor begins work at the operator's facilities. |
| 250.1905(a) | Language in §250.1905(a) should be revised to state: "You must ensure an initial hazards analysis (facility level) is or has been performed on each facility on or before (THE DATE 1 YEAR AFTER THE EFFECTIVE DATE OF THE FINAL RULE)". | Proposed §250.1905 is reflected in the final rule at §250.1911. The requirement to perform a hazards analysis for each facility within 1 year of the effective date of the final rule was retained. A previous hazards analysis may be used as long as it meets the requirements of API RP 75 and §250.1911 in the final rule. |
| 250.1905(a) | If an operator has not previously conducted a hazards analysis on all of his platforms, it may be impossible to complete a hazards analysis of all of his platforms within 1 year of the effective date of the final rule. A provision should be included for providing a prioritized list of facilities to the Regional Supervisor along with the date that each hazards analysis will be completed. This could be either in the rulemaking or a companion NTL. | BOEMRE disagrees. The final rule requires the operator to have its SEMS program in place within 1 year of the effective date of the rule. The hazards analysis requirement must be in accordance with the provisions of API RP 75, Section 3 and the requirements in this final rule under §250.1911, and included in the SEMS program. |
| 250.1905(a) | According to §250.1905(a), we must do a separate Hazards Analysis for every platform that we operate. Under our IMS, we get to the same place by doing a comprehensive hazards analysis (actually a more rigorous "risk assessment") of all of our operations, with evaluation and ranking of risks and planned mitigations. | There is nothing in the rule that prevents an operator from using the same hazards analysis for similar platforms. However, if one or more facilities are similar but have distinct differences that require discrete policies and procedures for safe operations meeting the SEMS elements, then you must develop a separate SEMS for each of those facilities. |
| 250.1905(a) | Element 1, "Hazards Analysis at the facility level" is already being achieved by following API RP 14C as a guideline for Analysis, Design, Installation, and Testing of Surface Safety Systems. The JSA/JHA along with the "Stop Work Authority" is already being utilized Gulf-wide. Furthermore, egress is identified in the platform submission process; chemicals and flammables kept on the facility are identified as part of the MSDS requirements; and mitigation of possible safety and health effects on employees are also already being performed. | BOEMRE agrees. The API RP 14C is a good guideline for conducting a hazards analysis for a production facility and it is referenced in API RP 75. However, the hazards analyses must follow API RP 75, Section 3, with clarification in §250.1911. |
| 250.1905(a)(1)(ii) | We do not understand the requirement that special attention should be given to any incident in which you were issued an INC, civil or criminal penalty; nor do we understand what "special attention" should cover; nor do we understand what length of time we should consider. Further, we have no idea how the enforcement action of a regulatory agency relates to hazards analysis. We agree that previous incidents related to the operation, to the extent known by the operator, should be evaluated regardless of whether or not they resulted in an enforcement action. It should be noted that in many cases, a facility may have had multiple previous operators and a complete history of previous incidents may not have been provided to the current operator. Recommendation: Strike the sentence "Special * * * penalty". | BOEMRE is incorporating by reference API RP 75. The operator must follow the guidelines under API RP 75, Section 3, as clarified in §250.1911. If BOEMRE evaluates a SEMS program, the operator must submit to BOEMRE a revised SEMS program that addresses any identified deficiencies. |
| | | This provision was amended, striking "special attention" while requiring the hazard analysis to address previous incidents. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
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| 250.1905(a)(1)(iv) | <p>It is not clear what BOEMRE's expectations are for a hazard review to cover coastal and marine environmental impact. These potential impacts are already covered in the environmental analysis conducted by BOEMRE for lease sales and exploration and development plans. The operator addresses these impacts in their EP, DOC, and OSRPs. This requirement is duplicative of analysis already conducted in accordance with the BOEMRE regulations in 30 CFR Part 250, subpart B, and 30 CFR Part 254.</p> | <p>The requirements for a hazards analysis are in API RP 75, Section 3 with clarification in §250.1911.</p> |
| 250.1905(a)(2) | <p>Recommendation: Strike coastal and marine environmental impacts from the accident scenarios list.</p> <p>Based on experience, a hazards analysis team is composed of (at least) individual(s) with experience in the operations being evaluated, and individual(s) who are experienced in the hazards analysis methodology. The rule states that these individuals need to have experience with both. That may be an impractical requirement.</p> <p>Recommendation: Change the second sentence to: "at least one person needs to be experienced".</p> | <p>The rule was changed to say "human and marine environment."</p> <p>The hazards analysis team must meet the requirements included in API RP 75, Section 3 and requirements necessary to implement API RP 75 in the final rule under §250.1911.</p> |
| 250.1905(b) | <p>There should be some prioritization in jobs/tasks to be evaluated. Everything an operator does is primarily a job/task. Routine jobs/tasks may be covered under operating procedures and the hazards analysis may be included in those procedures; therefore, a JSA may not be necessary. Jobs/tasks that are not routinely done and not covered by operating procedures should have a JSA. Jobs/tasks should be selected for analysis in priority order. We suggest the following prioritization:</p> | <p>BOEMRE agrees and has made the change to the final rule.</p> |
| <ol style="list-style-type: none"> 1. Jobs with highest rate of accidents or greatest potential for injuries 2. New jobs or non-routine jobs 3. Changes in process and procedures | <p>Recommendation: Remove section (b)(2)</p> | <p>BOEMRE agrees that an operator can prioritize its JSA to maximize safety as long as it meets the provisions of the final rule. BOEMRE removed JHA from the final rule. In the final rulemaking, JSAs are done for the immediate tasks at hand (not used for administrative or domestic services). If the particular activity is conducted on a recurring basis, and the parameters do not change, the person in charge of the activity may decide that a JSA for each individual activity is not required.</p> |
| 250.1905(b) | <p>The rulemaking also seems to envision that a "book" of JHAs/JSAs is maintained at the job site. While this may be true for jobs/tasks that are routinely performed, in many cases a JSA is completed for a non-routine task (e.g., an unusual lifting operation). The best JSAs are prepared by the workers on location and are handwritten. They should be kept in a manner that the workers can easily access them. The real value in the JSA is the "process" of the workers involved in the specific task actually discussing the hazards, agreeing on the individual roles and responsibilities and completing the JSA document. While it is important that JSAs for both routine and non-routine tasks be available for review by the workers until the job is completed, they may not be in a nice, neat, properly indexed book. We have no idea how the prescriptive documentation details in (b)(2) relate to keeping workers safe. They should be allowed to use whatever documentation technique works for them.</p> | <p>The requirement for an index was removed.</p> <p>We removed the requirement to maintain a book/index, but we require operators to keep a copy of the JSA for 30 days onsite and for 2 years at a location of the operator discretion and make them available to BOEMRE upon request.</p> <p>The requirements for JSAs are in the final rule, §250.1911.</p> <p>Recordkeeping and Documentation requirements are in §250.1928.</p> |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|---|---|
| 250.1905(b) | <p>The only element in the proposed regulation that attempts to address worker behavior is the task-specific “hazards analysis.” However, there is a lot of confusion throughout the regulated community about the terms “JHA” and “JSA.” We typically use the term “JHA” to mean a broad analysis of the hazards associated with a job or process. Such analysis is typically done by a diverse team and may be done in an office setting or at the job site. Many times, this analysis is included with a facility-level hazards analysis or operating procedures and in many cases covers routine tasks. We typically use the term “JSA” to be the analysis done by onsite workers immediately prior to performing a task, many times a non-routine task. Some workers start with a “go-by” and mark it up for the specific task at hand and others start with a blank piece of paper or form. We believe that the application of JSA has the best opportunity to impact worker behavior since it is the workers themselves that are identifying the hazards and developing plans, procedures, safeguards, etc., to avoid an incident.</p> | <p>The final rule distinguishes between a broad facility-based hazards analysis conducted in accordance with API RP 75, Section 3 and a task level JSA, §250.1911, as required in the final rule.</p> |
| 250.1905(b) | <p>Specific examples of practices within our IMS would be unacceptable under the proposed SEMS regulations: We presently conduct JSAs for work with at least some level of risk, but not for every work project and activity.</p> | <p>The operator is required to follow API RP 75 as incorporated by reference and perform JSA’s for those activities identified in its SEMS program, as addressed in §250.1911. There are routine tasks performed in the offshore environment that may meet the requirements of SEMS under the Safe Work Practices and Operating Procedures elements. However, for such activities that deviate from their norm due to a change in environment, personnel, or equipment-related factors, or other activities that are non-routine procedures, a JSA must be conducted that identifies and accounts for routine variations or the uniqueness of the activity.</p> |
| 250.1905(b) | <p>A commenter is concerned by the proposed requirement for a task-level JHA. While we understand that this may be more correctly described as a JSA, we believe that there needs to be a better understanding of both what constitutes a JSA, and for what tasks a JSA should be developed. Does BOEMRE expect a JSA for operation of a copy machine?</p> | <p>BOEMRE replaced the term JHA with JSA in the final rule. In the final rulemaking, JSAs are done for the immediate tasks at hand (not used for administrative or domestic services).</p> |
| 250.1905(b) | <p>Section 250.1905(b) states that a JHA must be performed for “each” work project and activity. BOEMRE must clarify this paragraph. There are many projects and activities that are considered “routine.” Our company wholeheartedly agrees that a thorough analysis should always be performed on all “non-routine” projects and activities. Our only concern is that a requirement for a JHA on all projects and activities would be overwhelming. The way the rule is written an operator would be required to perform a JHA for a simple activity such as obtaining tubing pressures or adjusting a level in a vessel.</p> | <p>There is nothing in the rule that prevents an operator from using the same JSA for a particular activity that is conducted on a recurring basis as long as the parameters of the activity do not change.</p> |
| 250.1905(b)(2) | <p>We further believe that the record retention requirements for the JSA and related index are unduly burdensome and contrary to BOEMRE’s stated intent that the programs not become a paperwork exercise. The proposal also creates concern regarding “ownership” of the JSAs/ index once a MODU is no longer under contract for the operator under whose contract they were developed</p> <p>Recommended: Strike this section.</p> | <p>The operator may use programs already in existence to comply with provisions of this final rule, as long as your SEMS program addresses all the elements in API RP 75 and the requirements in the final rule.</p> |
| 250.1906(a) | <p>We assume that the 13 requirements for procedures can be covered collectively by other management systems, especially with regards to chemicals and materials. The scope of these requirements (7, 9–13) goes beyond API RP 75, as well as OSHA PSM and EPA RMP.</p> | <p>The operator may use programs already in existence to comply with provisions of this final rule. BOEMRE is incorporating by reference API RP 75, Section 5 with requirements necessary to implement API RP 75 in §250.1913 to address operating procedures.</p> |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|-------------------------|--|---|
| 250.1906(a) | <p>Coupled with the requirement in §250.1905 to develop a SEMS for MODUs, §250.1906(a)(1) and (a)(5) would now require the operator to develop procedures for some drilling facilities that we neither own nor operate. This would significantly add to the documentation burden on the operators. We do not believe this would benefit the operator, the owner of the facility, or the personnel on the rig. Operators hire contractors that have safety programs in place and are in compliance with applicable laws, but do not dictate to them how to achieve that. The MODUs already have operations manuals developed in conformance with flag State requirements and/or IMO MODU Code and fall under the jurisdiction of the USCG. The proposed rule duplicates these requirements. Most operators do not have the resources or the expertise to develop operational procedures for drilling operations and depend on the contracted company who are the experts to develop their own procedures and safety systems.</p> <p>Recommendation: Change to “implement written production facility operating procedures”.</p> | <p>BOEMRE requires operating procedures for a MODU under BOEMRE’s jurisdiction. The operator’s operating procedures need to include provisions for evaluating operating procedures in their contractor plans. Under §250.1914 of the final rule operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator’s SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator’s facilities.</p> |
| 250.1906(a) | <p>It is easier to have site specific procedures that the operator can provide training to the contractor (preferably before the contractor employees begin work), and verify competency so that once the contractor’s employees reach the facility, there exists a clear understanding of what is to be done, and how to do it.</p> | <p>The operator is responsible for developing and implementing all operating procedures. Procedures should be site-specific for the task at hand e.g., drilling, cementing, coiled tubing. How operators decide to implement such operating procedures is up to them, as long as they are in compliance with API RP 75, Section 5, and the requirements in §250.1913 of the final rule.</p> |
| 250.1906(a) | <p>Our company agrees that operating procedures are a valuable tool in regards to paragraphs (1) through (13). Our only concern is that a written procedure for paragraphs (1) through (13) must be site specific. For example, a written procedure for paragraph (1) (initial startup) could only be followed for the facility that it was written for.</p> | <p>BOEMRE understands that standardizing procedures with respect to safe operations makes good sense where appropriate. An operator may do so regarding like facilities but it is the operator’s responsibility to identify any differences existing among similar SEMS facilities and identify those differences within their SEMS program. BOEMRE may require the operator to submit a complete SEMS for a particular facility should it deem the impact of the differences outweighs the similarities of the facilities.</p> |
| 250.1906(a)(1) | <p>Initial startup, startup following a turnaround, or startup after an emergency shutdown are redundant and encompass the same elements. We suggest they be combined.</p> | <p>BOEMRE disagrees and retained this paragraph in the final rule. We incorporated by reference API RP 75, Section 5 to address these terms.</p> |
| 250.1906(a)(3) | <p>What does BOEMRE envision as “temporary operations?” Please define or explain.</p> | <p>This paragraph was deleted from the final rule. Section 5 of API RP 75 does not define “temporary operations.”</p> |
| 250.1906(a)(4) | <p>Does the BOEMRE mean Emergency Shutdown Operations in (4)? If not, then please define “emergency operations”.</p> | <p>BOEMRE agrees that it should be addressed as “emergency shutdown operations”.</p> |
| 250.1906(a)(7) | <p>Bypassing and flagging should be included in the individual operating procedure; it is not a separate operating procedure in and of itself.</p> | <p>BOEMRE disagrees that “bypassing and flagging out of service” should be a separate operating procedure in and of itself.</p> |
| 250.1906(a)(7) | <p>We recommend the wording in §250.1906(a)(7) be changed from “bypassing and flagging” to “bypassing and flagging out of service”.</p> | <p>BOEMRE agrees that it should be addressed as “bypassing and flagging out of service.”</p> |
| 250.1906(a)(8) | <p>“Safety and environmental consequences of deviating from your equipment operating limits and steps required to correct or avoid this deviation;” is already covered by API RP 14C and is included in the individual operating procedures and is not a separate operating procedure in and of itself.</p> <p>Recommendation: Strike (a)(8)</p> | <p>BOEMRE disagrees with this comment and the operator must comply with the provisions of operating procedures listed in §250.1913(a)(8) and API RP 75, Section 5.</p> |
| 250.1906(a)(8–12) | <p>The intent of API RP 75 is to take environmental factors into consideration during startup, normal operations, temporary operations * * * not developing procedures specific to these issues. Specific environmental issues are covered under and or overlap with Hazardous Material Regulations, CERCLA, RCRA, H₂S regulations, and NPDES. These sections should be removed.</p> | <p>BOEMRE disagrees with this comment and the operator must comply with the provisions of operating procedures listed in §250.1913(a)(8) and API RP 75, Section 5. BOEMRE is incorporating by reference API RP 75. However, operators still must comply with other Federal laws and regulations.</p> |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|--|---|
| 250.1906(a)(13) | “Coastal and marine environmental impacts identified through your hazards analysis” is taken into account in the operating procedures themselves, they are not a separate operating procedure. Environmental impact identification is also covered in NPDES, air permit, and oil spill regulations and response plans. This section should be removed. | The overriding goal of SEMS is to protect the human and marine environment. |
| 250.1906(b) | Reword § 250.1906(b) to read, “Employees will have access to the appropriate procedures for their specific job/role in the operations.” This is subtle, but procedures for specific roles should be available to those specific employees, rather than all employees having access to all procedures. | BOEMRE disagrees and is keeping this and is incorporating by reference API RP 75, Section 5. |
| 250.1906(b) | We assume that procedures maintained electronically are considered accessible. | See API RP 75, Section 13 and § 250.1928. |
| 250.1906(b) | Please state what you mean as “accessible.” The facility where the work is conducted may be manned or unmanned. We suggest that the operating procedures be kept at the nearest manned facility. | The API RP 75 does not address this issue and the operator should define, in their SEMS, where operating procedures are to be kept. However, you must be able to provide your SEMS to BOEMRE upon request in a timely fashion. |
| 250.1906(d) | What specifically is meant by, “develop and implement safe and environmentally sound work practices for identified hazards during operations?” Is this meant to be Safe Work Practices (e.g., Hot Work, Confined Space, SIMOPS, etc.), or some other processes? This seems to be the intent of this whole element, if not all of the SEMS rule. | The intent of the SEMS rule is to ensure safe work practices for all operations on an OCS facility. |
| 250.1907 | Is the intent of the mechanical integrity element to cover critical equipment as referred to in API RP 75? The way it is worded this element may cover more: “Your mechanical integrity program must encompass all equipment and systems used to prevent or mitigate uncontrolled releases of hydrocarbons, toxic substances, or other materials that may cause environmental or safety consequences.” What are the types or severity of such consequences? | The final rule incorporates by reference API RP 75, Section 8 that addresses critical equipment and includes requirements necessary to implement API RP 75 in § 250.1916. It is the operator’s responsibility to meet the intent of SEMS as well as its requirements. The overriding goal of SEMS is to protect the human and marine environment. The inventory of harmful substances on offshore facilities is well known but will also evolve over time so it is incumbent upon the operator to keep all harmful substances controlled and contained. |
| 250.1907 | Does BOEMRE expect each operator to implement a mechanical integrity program for each MODU that we contract to work on our lease that we neither own nor operate? The MODU operator should have a mechanical integrity program for his equipment. The operator should verify that the MODU operator has such a program. Recommendation: You must develop and implement written procedures that provide instructions to ensure the mechanical integrity and safe operation of equipment through inspection, testing, and quality assurance for equipment on your facility used to prevent or mitigate uncontrolled releases of hydrocarbons, toxic substances, or other materials that may cause environmental or safety consequences. For MODUs operating on your lease, you must verify that the MODU operator has a mechanical integrity program that meets the requirement in this subpart. These procedures must address the following: | BOEMRE requires operating procedures for a MODU under BOEMRE’s jurisdiction. The operator’s operating procedures need to include provisions for evaluating operating procedures in their contractor plans. Under § 250.1914 of the final rule operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator’s SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator’s facilities. |
| 250.1907 | Include the requirements in § 250.1907(i) in § 250.1907(a) | BOEMRE disagrees and in the final rule will keep both sets of requirements separate. |
| 250.1907 | A contractor can have a mechanical integrity program for contractor owned equipment (tools, vehicles, etc.), but to address the operator’s equipment, again, it is more practical for the operator to develop this program, then train the contractor in implementation. | BOEMRE agrees. The operator must have a mechanical integrity program in accordance with the requirements of API RP 75, Section 8 and § 250.1916. |
| 250.1907 | This entire element is already being addressed. Paragraph (a) is already addressed by API RP 14C. Paragraph (b) (training) is already being addressed as part of the subpart O requirement. Paragraphs (c) through (i) is being addressed through the requirements of API RP 14C along with the monthly, quarterly, semi-annual, and annual testing of the surface and sub-surface safety system. | BOEMRE disagrees. Subpart O addresses training related to well control and production safety. We incorporated by reference API RP 75, Section 8 and § 250.1916 to address mechanical integrity. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|---|--|
| 250.1907(a) | We suggest replacing “manufacturers design and material specifications” with “applicable design and material specifications.” The design, procurement, fabrication, etc., of equipment are not necessarily just based on manufacturers’ specifications but could be based on API, company, or other applicable design and material specifications. | We disagree; we believe that the manufacturer’s design and material specifications are the most appropriate guidance to use. |
| 250.1907(b) | Please note that there are typically no manufacturers recommended inspection intervals for fixed equipment (pressure vessels, piping, pipelines). Maintenance intervals should be allowed to be extended based on component history, operating experience, and risk-based decision making. | BOEMRE is incorporating by reference API RP 75, Section 8 and §250.1916 to address mechanical integrity. The operator’s maintenance program must be structured to enhance safety and protect the environment and must sustain ongoing mechanical integrity. Testing and inspection procedures must follow commonly accepted standards and codes, such as API 510 and the manufacturer’s recommendations. |
| 250.1907(b) | Equipment may be maintained by employees, contractors, or a mix. Some specialized equipment is actually maintained by the manufacturer’s representatives who periodically travel to offshore facilities to perform required maintenance. Therefore, our employees do not need to be trained to do the actual maintenance work for all equipment in the mechanical integrity program. Recommended: Replace (b) with the following: The training of maintenance workers in the application of the procedures, relevant hazards, and safe work practices. | The operator must have mechanical integrity in accordance with API RP 75, Section 8 and §250.1916, in their SEMS program. Your contractors must conduct operations in accordance with your SEMS program. |
| 250.1907(c) | We recommend deleting the language “meet the manufacturer’s recommendations” in §250.1907(c). Many of our inspection and testing requirements, while meeting regulations, are risk-based in approach. | We disagree, we believe that the manufacturer’s recommendations are appropriate to use. |
| 250.1907(c) | Specific examples of practices within our IMS would be unacceptable under the proposed SEMS regulations: We presently feel free to inspect or test some equipment more frequently than necessary to gain some extra level of comfort, but we do not expect to be locked into a greater frequency. | The operator is required to meet or exceed the inspection frequencies in 30 CFR part 250. |
| 250.1907(d) | Is electronic documentation of the person performing the inspection or test acceptable? Electronic work order systems are often used to schedule and document inspections and tests. | To address recordkeeping and documentation, we incorporated by reference API RP 75, Section 13, and additional reporting and documentation requirements in §250.1928. Electronic records are acceptable to BOEMRE for most records. |
| 250.1907(d) | We recommend adding, “Electronic documentation of the same information will suffice to meet this requirement” to §250.1907(d). The requirement for “signature” on inspection or test documentation should be modified to encompass operators’ use of electronic work management systems. Work orders, assigned to and completed by individuals within the software should be acceptable. | BOEMRE kept this paragraph in the final rule. The final rule will also address mechanical integrity documentation as described in API RP 75, Section 8. Electronic records are acceptable to BOEMRE for most records, including electronic signatures. |
| 250.1907(d) | The last sentence in §250.1907(d) should be modified to place an “or” between inspection and test, therefore changing the language to read “and the results of the inspection or test”. | BOEMRE agrees with this comment and made the text change in new §250.1916(d). |
| 250.1907(e) | Correction of deficiencies before further use will prevent use of risk-based decision making, and the subsequent shut-in of operations may present additional hazards. Would this apply in the case of waiting on parts and while mitigation measures are put in place? Does it cover deficiencies that may not affect operations integrity? Run to failure should be a viable option for some components. Suggest this requirement be based on risk. This is not a requirement in API RP 75. | Deficiencies are addressed in API RP 75, Section 8 and §250.1916(e). Under the final rule, the procedures for Mechanical Integrity must address the correction of deficiencies associated with equipment and systems that are outside the manufacturer’s recommended limits before further use. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|--|--|
| 250.1907(e) | Specific examples of practices within our IMS that would be unacceptable under the proposed SEMS regulations: We presently decide whether to take a piece of equipment out of service based upon our judgment of actual risk (likelihood and consequence of failure). | Under §250.1916(e) of the final rule the operator must document the procedures to correct critical equipment deficiencies or operations. The operator may continue to use an IMS, if it meets the requirements of API RP 75 and the final rule and the operator addresses any deficiencies. We cannot accept <i>only</i> “judgment” as a means of the operator determining risk. The operator must account for what factors were considered in taking equipment out of service. This does not have to be an exhaustive analysis but it does need to reflect that all relevant SEMS elements were considered. Documenting the “likelihood and consequence of failure” comports with the intent of SEMS. |
| 250.1907(f)–(i) | How is this requirement different from (a), nor how it is to be implemented. Recommendation: Strike (f). How is this requirement different from (a), nor how it is to be implemented. Recommendation: Strike (g). Since BOEMRE has outlined prescriptive requirements for the inspection and testing and the documentation of those inspections and tests, we do not understand what the requirement in (h) is and how it is different from (c) and (d) above or how to implement it. Recommendation: Strike (h). We suggest this be included under (a). Recommendation: Strike (i) and include under (a). | BOEMRE disagrees with this comment and is incorporating by reference API RP 75 and requirements necessary to implement API RP 75 in the final rule. The operator must follow the requirements of API RP 75, Section 8 and the requirements in §250.1916 for mechanical integrity. Paragraph (a) of §250.1916 provides an overview of the requirements, while the subsequent paragraphs provide more details. |
| 250.1908 | There is no mention if the MOC is for either permanent and temporary changes or just permanent changes. Please clarify. | The operator must follow the requirements of API RP 75, Section 4 and §250.1912 of the final rule for MOC, which requires procedures for any changes related to equipment, operating procedures, personnel changes, materials, and operating conditions, except for replacement in kind. This applies to permanent and temporary changes. |
| 250.1908 | A production contractor can have a MOC process, but in order for the process to work, the operator (client) must be part of the process. The scenario of the lessee/operator having a MOC process that the contractor can be a part of is a better model. | The operator is responsible for developing and implementing a MOC in accordance with API RP 75, Section 4 and §250.1912 of the final rule. The operator is responsible for coordinating with the contractor regarding MOC. The operator must ensure that their contractor embraces safety principles that support their SEMS program. The MOC is a cooperative activity that makes all parties responsible for its success. |
| 250.1908(a)(2) | A process for changing operating procedures has already been established in §250.1906(c). The MOC process should simply identify that operating procedures either need to be changed (or don't) as a result of changes to the facility. The actual change to the operating procedures should not have to go through the MOC process. | BOEMRE is incorporating by reference API RP 75, Section 4 for MOCs and Section 5 for Operating Procedures and requirements under §§250.1912 and 250.1913 of the final rule. Under §§250.1912 and 250.1913, the operator must address MOC for operating procedures. |
| 250.1908(a)(3) | Section 250.1908 proposes issuing MOCs for personnel changes, but does not define which personnel that encompasses. It would be quite onerous if a MOC was required for every single individual that was changed out on a facility. To provide clarity as to those personnel changes that would require a MOC, we propose adding the following language to §250.1908(3): “Personnel with specific knowledge or experience who supervise or operate, or support operations of a facility which would lead to a loss of knowledge or experience”. | BOEMRE disagrees with this comment and it is the operator's responsibility to address personal changes. BOEMRE is incorporating by reference API RP 75, Section 4 and requirements under §250.1912, to address MOCs for changes in personnel. API RP 75, Section 4 includes the suggested language. The definition of contractors in §250.1914(a) does not include those providing domestic services. |
| 250.1908(a)(4) | What does BOEMRE envision as a change in material that requires a MOC that is not already covered under equipment? | BOEMRE is incorporating by reference API RP 75, Section 4 and requirements under §250.1912 to address MOCs. The operator must adopt these requirements in the SEMS. Materials that are not covered under equipment could include process chemicals and maintenance materials; these are mentioned in API RP 75. |
| 250.1908(a)(5) | We assume that changes in operating conditions include such things as changes to the operating envelope (pressure, temperature, flow rates, material chemistry, etc.) as described in the facility design basis or a change in the chemistry of the product that was not considered in the equipment specification. If our assumption is not correct, please clarify. | BOEMRE is incorporating by reference API RP 75, Section 4 and requirements under §250.1912 to address MOCs. API RP 4.2e addresses changes in operating conditions. The operator must adopt these requirements in the SEMS. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
|------------------------|--|---|
| 250.1908(c) | What does BOEMRE envision by the following requirement: "You must review all changes prior to their implementation?" | BOEMRE is incorporating by reference API RP 75, Section 4, and requirements under § 250.1912 to address MOCs. Section 250.1912(c) requires the operator to review all changes prior to their implementation and API RP 75 section 4.3 addresses this review related to changes in personnel. This review is required to ensure the safety of personnel. |
| 250.1908(c) | Specific examples of practices within our IMS that would be unacceptable under the proposed SEMS regulations: We presently allow immediate approval of work considered to be for emergency situations without prior MOC review and approval, subsequently working through MOC as a follow-up. | BOEMRE is incorporating by reference API RP 75, Section 4 and requirements under § 250.1912 to address MOCs. The operator may continue to use an IMS, if it meets the requirements of API RP 75 and the final regulation. Emergency situations are addressed in the final rule under § 250.1918 and requires the operator to have emergency response and control plans in place and ready for immediate implementation. |
| 250.1908(f) | We assume that the documentation for this step will be under § 250.1906(c). | If the management of change results in change in the operating procedure, this change must be documented as provide in § 250.1912(f) in the final rule. |
| 250.1909 | The final rule must distinguish between "contractor employees" and "contracted employees". | While BOEMRE does not directly regulate the operator/contractor relationship, it is the responsibility of both the operator and contractor to conduct activities so that they comport with the operator's SEMS. |
| 250.1909 | <p>1. How does this part relate to subpart O?</p> <p>2. This section could conflict with subpart O and become detrimental to operators.</p> | <p>1. Subpart O specifically applies to personnel involved in well control and production safety system operations, while subpart S applies to all aspects of OCS operations under BOEMRE jurisdiction.</p> <p>2. BOEMRE disagrees. Subpart O complements a SEMS program. The operator may use the training requirements of subpart O to meet the SEMS requirements in API RP 75 Section 7 as incorporated by reference and the requirements in § 250.1915.</p> |
| 250.1909 | <p>BOEMRE already has regulations in place to address training and competency assessments for both operator employees and contractors. 30 CFR Part 250, subpart O, Well Control and Production Safety Training, clearly states that operators must ensure that both employees and contract personnel understand and can properly perform their duties; § 250.1503(b)(3) requires operators to have procedures "for verifying that all employees and contractor personnel engaged in well control or production safety operations can perform their assigned duties." In fact, BOEMRE periodically assesses the Subpart O program by auditing and testing as described in § 250.1507(d), which states "BOEMRE or its authorized representative may conduct testing at either onshore or offshore locations. Tests will be designed to evaluate the competency of your employees or contract personnel in performing their assigned well control and production safety duties. You are responsible for the costs associated with this testing, excluding salary and travel costs for BOEMRE personnel".</p> <p>We find that the proposed language in § 250.1909 is redundant with existing regulations under 30 CFR Part 250, subpart O, and therefore, should be eliminated from the proposed rule. If you do not agree, then please clarify the relationship between this proposed rule and the requirements in subpart O and identify what contractor groups have otherwise not been addressed by the existing subpart O requirements. If BOEMRE has concerns regarding contractor selection or competency, then the appropriate regulation to address such concerns is within the subpart O program.</p> <p>Recommendation: Strike § 250.1909 in its entirety.</p> | <p>BOEMRE disagrees. The SEMS rule applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on or adjacent to a covered process. This section was renumbered as § 250.1914 in the final rule. The operator is responsible for obtaining and evaluating information regarding the contract employer's safety performance and programs and informs contract employers of the known potential fire, explosion, or toxic release hazards related to the contractor's work and the process. The operator may use the training requirements of subpart O to meet the SEMS requirements in API RP 75, Section 7, as incorporated by reference and § 250.1915.</p> <p>BOEMRE disagrees. Subpart O complements a SEMS program. All personnel with the operator's SEMS program need to be trained to competently perform their assigned duties. The operator may use the training requirements of subpart O to meet the SEMS requirements in API RP 75, Section 7, as incorporated by reference and § 250.1915 in the final rule.</p> |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
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| 250.1909 | <p>The current BOEMRE regulations under subpart O at §250.1500 require operators to ensure and document that their company and contract employees are competent to perform their assigned jobs. Therefore, the section on contractor selection and competency in the proposed rule is redundant and not needed. If BOEMRE felt it necessary, subpart O could be expanded to include any worker groups not already covered in the current rule. In the event BOEMRE proceeds with an entirely new rulemaking, we recommend a performance-based rule be written (like subpart O) to allow operators to utilize their existing safety and environmental management programs instead of a detailed, prescriptive program as proposed in this rulemaking. Companies could then certify to BOEMRE that their programs include the required elements and use their documentation and audit systems that are already in place and working.</p> | <p>Subpart O specifically applies to personnel involved in well control and production safety system operations. The SEMS rule applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on, or adjacent to, a covered process. This section was renumbered as §250.1914 in the final rule. The operator is responsible for obtaining and evaluating information regarding the contract employer's safety performance and programs and informing contract employers of the known potential fire, explosion, or toxic release hazards related to the contractor's work and the process. The operator may use the training requirements of subpart O to substantially meet the SEMS requirements in API RP 75, Section 7, as incorporated by reference and the requirements necessary to implement API RP 75 in §250.1915. The contractor must ensure that all personnel not mentioned in subpart O are also competent in conducting their job and subscribe to safe work practices as identified in the operator's SEMS program.</p> |
| 250.1909 | <p>While the proposed rule states the required SEMS program must include each of the 4 elements described, we believe the §250.1909 "What criteria must be documented in my SEMS program for contractor selection?" is actually a 5th element that has been added without the justification and rationale used to validate inclusion of the other 4 elements.</p> | <p>BOEMRE disagrees; SEMS must include everyone working on a facility; criteria for contractor selection are an important part of that. Contractor criteria are addressed in Section 6.4 and Appendix A of API RP 75 as incorporated by reference. We included this in the final rule with requirements necessary to implement API RP 75 in §250.1914.</p> |
| 250.1909 | <p>If contractors are to be "accountable" for SEMS activities, their scale, complexity and scope of work should also be taken into account. Example: Contractor services vary from "Labor" (i.e., production operators), "Equipment" (i.e., Generators, machinery rentals) or both "Labor and Equipment" (i.e., drilling rig, welding machine, and welder), etc. A contractor supplying "Labor" services should not be required to have a SEMS program, but the competency to work within the clients program (i.e., perform JSAs, initiate MOC process, utilize Operating Procedures in performance of duties, perform level one visual Mechanical Integrity inspections in accordance with a lessee's SEMS program). A contractor only supplying "Equipment" should have a Mechanical Integrity Plan and Operating Procedures that accompany the equipment and limited hazards analysis pertaining to his equipment. A contractor supplying "Labor and Equipment" should have a SEMS program that covers his equipment and the operation thereof.</p> | <p>The operator is responsible for having a SEMS program in place. The operator is responsible for coordinating with the contractor regarding their SEMS program. The operator must ensure that their contractor embraces safety principles that support their SEMS program.</p> |
| 250.1909 | <p>There is no indication in the data used for the proposed rule that "Contractor Selection" contributed to the incidents analyzed by the BOEMRE.</p> | <p>Contractors perform a majority of the work on the OCS and the selection of skilled, knowledgeable, and trained contractor personnel by the operator is an important part of ensuring that the SEMS program works.</p> |
| 250.1909 | <p>The proposed rule would require the lessee/operator to develop a SEMS. However, §250.1909 states that the lessee must document that their contractors have policies and practices that are consistent with the lessee's plan. Furthermore, it states that a copy of the contractor's SEMS program must be kept by the operator and the contractor at each facility where contract operations are being performed. Our company has 50 to 60 customers. To strive for consistency with 50 to 60 individual programs is unrealistic and places an unnecessary burden on all contract operators. Our company either manages or operates over 600 platforms in the GOM. The paperwork burden of supplying and maintaining a SEMS program for each facility (again, consistent with that individual customer) could only be done at a tremendous cost of not only man hours but monetary investment that may not be recoverable.</p> | <p>The operator is responsible for having a SEMS program in place. The operator is responsible for coordinating with the contractor regarding their SEMS program. The operator must ensure that their contractor embraces safety principles that support their SEMS program. Under §250.1914 in the final rule the operators must obtain and evaluate information regarding the contractor's safety and environmental performance when selecting a contractor. Operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator's SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator's facilities.</p> |

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| 250.1909 | There is absolutely no need for further expansion of contractor selection and contractor documentation in any SEMS program. Subpart O already addresses contractor evaluations and contractor selection. This portion of the proposed rule is redundant and attempts to expand once again on the definition of "Production Operations". | Subpart O applies to personnel involved in well control and production safety system operations. Section 250.1914 of the final rule applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on, or adjacent to, a covered process, as well as Appendix A of API RP 75. The operator is responsible for verifying that contractor personnel can perform their assigned duties and informs contract employers of all hazards related to the contractor's work and the process. The operator may use the training requirements of Subpart O to meet the SEMS requirements in API RP 75 Section 7 as incorporated by reference and § 250.1915 of the final rule. |
| 250.1909 | BOEMRE cannot expect the operator or lessee to evaluate, test, and document the competency of these hired professionals as they are by name certified to perform their tasks and possess unique knowledge. Additionally, contractor selection does not affect human factors. | BOEMRE disagrees. The operator is accountable for contractor personnel activities and equipment. BOEMRE does not expect the operator to test their contractors. BOEMRE does expect the operator to evaluate their contractor's ability to perform the job that they are hired to do and to document that they have done so. Under § 250.1914 in the final rule the operators must obtain and evaluate information regarding the contractor's safety and environmental performance when selecting a contractor. Operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator's SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator's facilities. |
| 250.1909 | We are concerned with the ambiguous language related to contractors and contracted personnel. BOEMRE fails to clearly distinguish between contracted individuals acting in the same capacity as an employee, and companies contracted to perform specialized services for a lessee, leading to perhaps unintended applications. For example, § 250.1909(a) of the proposed rule states, "A contractor is anyone performing work for the lessee." This could be construed as including emergency response operations even though these are not integral to oil and gas exploration and production operations. We support the OOC comment that the section relating to contractors be stricken from the rule, as redundant with existing subpart O regulations. In the alternative, we request that the currently overbroad language be clarified to define contractors, and contracted personnel, and to confirm that the rule does not apply to emergency response contractors even though they are contracted to perform work for a lessee in the OCS. | BOEMRE disagrees. Subpart O applies to personnel involved in well control and production safety system operations. Section 250.1914 of the final rule applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on, or adjacent to, a covered process and Appendix A of API RP 75. The operator is responsible for obtaining and evaluating information regarding the contract employer's safety performance and safety programs and informs contract employers of the known potential fire, explosion, or toxic release hazards related to the contractor's work and the process. The operator may use the training requirements of subpart O to meet the SEMS requirements in API RP 75, Section 7 as incorporated by reference. The API RP 75 defines contractor as "The individual, partnership, firm, or corporation retained by the owner or operator to perform work or provide supplies or equipment. The term contractor must also include sub-contractors". |
| 250.1909 | The data used in the proposed rule makes no mention of problems regarding contractor competency, training, MOC, mechanical integrity, etc. | Contractors perform the majority of the work on the OCS and as such, selecting skilled, knowledgeable, and trained contractor personnel by the operator will help achieve safe OCS operations. Under § 250.1914 in the final rule the operators must obtain and evaluate information regarding the contractor's safety and environmental performance when selecting a contractor. Operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator's SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator's facilities. |
| 250.1909(b) | 1. Are electronic copies of contractor's competencies and SEMS programs acceptable? | 1. Electronic copies of contractor's competencies and SEMS programs are acceptable. See API RP 75, Section 13 and § 250.1928. |

| Proposed rule citation | Comment received on proposed rule | BOEMRE response to comment |
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| | 2. Do we need to keep competencies for each individual contractor? | 2. In §250.1914 of the final rule, the SEMS must include procedures and verification that the operator’s contractor and employees understand and can perform their assigned duties, as well as Appendix A of API RP 75, which addresses contractor selection criteria. The operator is responsible for ensuring and validating the competency of their contractors; the method for doing so must be detailed in their SEMS program. The operator may request specific performance information from contractors. |
| 250.1910 | We recommend that the prescriptive language be replaced with the following: “You must audit your SEMS program in accordance with API RP 75, Section 12, Audit of Safety and Environmental Management Program Elements”. | BOEMRE incorporated by reference API RP 75, Section 12 and requirements necessary to implement API RP 75 in the final rule under §250.1920 to address audits and documentation. The final rule gives the option of utilizing either an independent third party or your designated and qualified personnel to conduct audits on your behalf. |
| 250.1910(a) | We believe timing for audits should be based on performance and risk rather than a prescribed schedule as described in §250.1910(a). | BOEMRE incorporated by reference API RP 75. Audit frequency is addressed in §250.1920 of the final rule. The operators must have their SEMS programs audited by either an independent third party or your designated and qualified personnel to conduct audits on your behalf according to the requirements of this subpart and API RP 75, Section 12 within 2 years of the initial implementation of the SEMS program and at least once every 3 years thereafter. |
| 250.1910(b) | As part of our SEMS program, we audit all facilities (off-shore and on) on a 3–5 year basis and roll up results of audits from each year to evaluate our program as a whole. We assume this is acceptable in accordance with this section. | Audit frequency is addressed in §250.1920 of the final rule. The operators must have their SEMS programs audited by either an independent third party or your designated and qualified personnel to conduct audits on your behalf according to the requirements of this subpart and API RP 75, Section 12 within 2 years of the initial implementation of the SEMS program and at least once every 3 years thereafter. |
| | Which part of this audit process would the BOEMRE want to be invited to participate/observe? | In §250.1920(b), the operator must notify the BOEMRE 30 days in advance to allow BOEMRE to participate in/observe the operators SEMS audit. BOEMRE may participate or observe the audit of any of the elements in the final rule. |
| 250.1910(b) | We recommend deleting language at §250.1910(b) requiring notification to BOEMRE prior to conducting an audit. | BOEMRE disagrees; we maintained this requirement in the final rule, so that BOEMRE may observe SEMS audits under §250.1924(c). |
| 250.1910(b) | How does BOEMRE envision participating in an audit as just as an observer? These seem to be contradictory terms. If BOEMRE is merely going to observe and not do or say anything, then perhaps better wording would be “Representatives from BOEMRE may observe your SEMS audit.” Further, if BOEMRE is going to simply observe, what is the purpose of observing the audit? | If BOEMRE decides to participate in a SEMS audit, our activities may include one or more of the following: <ul style="list-style-type: none"> • Observation. • Requesting documentation. • Revising SEMS program. • Other duties as needed. |
| 250.1910(b) | The wording in this section also seems to indicate that the SEMS audit will be conducted in a meeting style; otherwise, how will BOEMRE observe the audit? | BOEMRE may participate as observers to verify compliance. BOEMRE may issue warnings, PINCs, or INCs, under §250.1927. BOEMRE disagrees. In the final rule BOEMRE may participate in the audit in the field and office locations as needed. How BOEMRE participates in the audit will be based on how the operator conducts its audit. |
| 250.1910(b) and (c) ... | Will the BOEMRE write INCs on the issues self-discovered on audits (either as a participant or following review of the audit report)? | BOEMRE may write INCs based on the severity of the issues discovered during an audit (either as a participant or following the review of the audit report). If the BOEMRE discovers an issue when reviewing the audit report, we will consider whether the extent to which the operator has addressed the issue when deciding if we should write an INC. BOEMRE will consider all relevant factors when considering issuing an INC, including the fact that the operator self-discovered the deficiency. BOEMRE encourages operators to identify deficiencies during their audits and looks favorably on audits detailing such, before deciding if a self-discovered deficiency warrants receiving an INC. BOEMRE recognizes the intent of the operator’s audit is to find deficiencies and make the necessary corrections to enhance safety and BOEMRE does not intend for audits to be used as a punitive exercise. |

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| 250.1910(c) | When does BOEMRE consider the audit to be completed? We consider the audit to be completed when the final audit report is issued. | The audit is complete when any deficiencies in a SEMS program are corrected and documented. If there are no deficiencies, the audit is complete when the final audit report is issued and submitted to BOEMRE. |
| 250.1910(c) | Given the language in §250.1910(d), it appears that BOEMRE does not envision receiving the actual SEMS audit report. Recommendation: You must submit a report to the BOEMRE within 30 days after the issuance of the final SEMS report by your designated and qualified personnel or your independent third-party. The report need not be the full SEMS report but must outline * * *. | In §250.1920 of the final rule, the operator must require the Independent Third Party to submit an audit report of the findings and conclusions of the audit to BOEMRE within 30 days of the audit completion date. The report must outline the results of the audit, including deficiencies identified. |
| 250.1910(c) | We agree with the BOEMRE proposal to periodically review the results of SEMS audits based on operator performance through unannounced or announced inspections. However, we are not supportive of the language at §250.1910(c) that requires producing a separate report solely for BOEMRE purposes within 30 days of the completion of an audit. This is an administrative burden and does not meet the intent of the proposed regulation that the rule not be a paperwork exercise. We suggest adding language to §250.1910(c) that BOEMRE could review audit reports during inspections or upon request that would provide BOEMRE unimpeded access to any audit findings at their discretion. | The audit reports are critical documents that BOEMRE needs to ensure that your audit protocols are true to the intent of this subpart and that any deficiencies have been addressed appropriately and in a timely manner. In §250.1920 of the final rule, the operator must require the Independent Third Party or your designated and qualified personnel to submit an audit report of the findings and conclusions of the audit to BOEMRE within 30 days of the audit completion date. The report must outline the results of the audit, including deficiencies identified. |
| 250.1910(d) | What does BOEMRE envision as the difference between verifying corrective actions from an audit in §250.1910(d) and §250.1913? | There is not a significant difference between the two sections in regards to verifying corrective actions. |
| 250.1910(e) | What is the purpose of retaining copies of the audit for 5 years, when the program has to be audited every 3 years? Recommendation: You must retain copies of either the independent third-party's SEMS records or self audit for a minimum period of 3 years or until the completion of the next audit. | BOEMRE is incorporating by reference API RP 75, Section 12 and §250.1920 of the final rule will require independent Third Party or your designated and qualified personnel to conduct audits on your behalf. The final rule has additional recordkeeping requirements that are not in API RP 75. In §250.1920 of the final rule, the operator must require the Independent Third Party or your designated and qualified personnel to submit an audit report of the findings and conclusions of the audit to BOEMRE within 30 days of the audit completion date and to keep copies of the audits for 6 years. Requiring the operators to keep the audits for 6 years ensures that they have copies of audits for at least 2 audit cycles for reference. |
| 250.1911 | We recommend that the prescriptive language be replaced with the following: "Your SEMS program procedures and documents must be maintained in accordance with API RP 75, Section 13, Records and Documentation". | BOEMRE incorporated by reference API RP 75, Section 13, and additional recordkeeping and documentation requirements in §250.1928. |
| 250.1911 | Which records need to be kept to comply with this part? Which records need to be signed and dated? Only those records specifically referred to in this proposed rule? API RP 75 provides guidance and examples for this section. | The response to these questions are addressed in API RP 75, which BOEMRE incorporated by reference, and additional recordkeeping and documentation requirements in §250.1928. |
| 250.1911 | The proposed regulation has exhaustive prescriptive documentation and recordkeeping requirements imbedded throughout the rule. Existing programs will have to be rewritten by all operators to incorporate these prescriptive requirements. We do not believe that this level of prescriptive documentation and recordkeeping will increase safety. The API RP 75 has a records and documentation section. If BOEMRE is going to require documentation and recordkeeping, then again, we strongly recommend that Section 13 of API RP 75 be adopted in the final rulemaking. | BOEMRE incorporated by reference API RP 75, Section 13, and additional recordkeeping and documentation requirements in §250.1928. |
| 250.1912(c) | When will BOEMRE evaluate the independent third-party? Before or after they are used for a SEMS audit? What is the evaluation criterion? If BOEMRE finds deficiencies in the third-party and they have already performed a SEMS audit, does that put the audit results in jeopardy or require a new audit be performed? | The operator must use an independent third-party or your designated and qualified personnel performing independent third party functions. BOEMRE will not approve, but will evaluate, the independent third-party or your designated and qualified personnel; however, if there are deficiencies in the audit, we will take appropriate action. The independent third-party or your designated and qualified personnel must meet the requirements of §250.1926. |

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|------------------------|---|---|
| 250.1913(a) | <p>“Adequate” and “effective” are very subjective terms. What criteria will BOEMRE utilize to determine if a program is adequate and/or effective? Many operators currently have well-developed programs, but may still have injuries and incidents. Would these programs be deemed adequate and effective?</p> <p>Recommendation: (a) BOEMRE or its authorized representative may evaluate or visit your facility to determine whether your SEMS program is in place and being followed. These evaluations or visits may be random or based upon the OCS lease operator’s or contractor’s performance.</p> | <p>In the final rule, BOEMRE removed the term “adequate” and adopted most of the recommended language. This is now in §250.1924.</p> |
| 250.1913(a) | <p>BOEMRE is in a much better position, than a third-party company to approve the lessee’s SEMS Programs for the following reasons:</p> <ol style="list-style-type: none"> 1. BOEMRE is a government agency and therefore does not have a conflict of interest. Whereas a third-party company is a for-profit entity and will be subject to the pressures of financial interest. Additionally, third-party companies could be approving programs that they have produced. 2. BOEMRE has ready access to all offshore leases. | <p>The final rule will require operators to use an independent third-party or designated and qualified personnel performing independent third party functions to audit a SEMS program. BOEMRE will not approve SEMS programs because the intent is to have a program that evolves and adapts, as needed. This allows operators to tailor the program to their individual needs and corporate cultures on an ongoing basis.</p> <p>Under § 250.1925 of the final rule, BOEMRE may conduct an audit if BOEMRE identifies safety or non-compliance concerns based on the results of our inspections and evaluations, or as a result of an event.</p> |
| 250.1913(b) | <p>What are the qualifications of the BOEMRE representatives conducting these evaluations? Are they familiar with management systems and auditing protocols?</p> | <p>BOEMRE will use appropriate BOEMRE personnel with the proper credentials and training to ensure consistency.</p> |
| 250.1914 | <p>We have serious concerns about the consistency of enforcement actions. How will BOEMRE ensure the consistency of evaluation?</p> | <p>BOEMRE continually works to address inconsistency. We have demonstrated improvements in this area for the last 10 years. BOEMRE has established internal processes to help ensure consistency in enforcement.</p> |
| 250.1915 | <ol style="list-style-type: none"> 1. Please provide detailed instructions and examples for filling out MMS–131. 2. Who within BOEMRE is the form to be sent to and by what method * * * paper, electronic, etc.? 3. By calendar year, we assume that you mean Jan 1 to Dec 31. If not, please clarify. 4. Please state how BOEMRE will utilize the data 5. Please include provisions for holding the individual company data confidential. 6. We also point out the authority to require employers to collect and report work-hours and injury/incident data of this type actually rests with the USCG based on the MOU between USCG and OSHA dated 19 December 1979. Furthermore, the collection and reporting of injuries and illnesses on the OCS falls under the currently pending USCG rulemaking (RIN 1625–AA18) issued on 27 June 1995, and entitled Outer Continental Shelf Activities. Coordination by BOEMRE with the USCG is recommended to consolidate and coordinate their efforts and avoid any duplication of requirements and unnecessary burdens. | <ol style="list-style-type: none"> 1. See Appendix I in preamble of the final rule. 2. The form may be sent to the Safety and Enforcement Branch by fax to (703) 787–1575, by e-mail to <i>semp@BOEMRE.gov</i>, or by mail to 381 Elden St., MS–4023, Herndon, VA 20170. 3. For this application, the BOEMRE considers a calendar year to cover the time from January 1st to December 31st. 4. BOEMRE uses the data collected in Form MMS–131 to calculate 20 annual, OCS-wide, performance indices. The indices provide information about performance and safety trends; they also allow OCS operators to compare their performance with industry averages. 5. The information on Form MMS–131 is not protected from disclosure and is subject to FOIA should a member of the public request this information. 6. BOEMRE disagrees. The OSHA does not have authority for OCS oil and gas and sulphur activities. |

The following lists the citation for the proposed rulemaking and what the current citation is in the final rulemaking.

| Proposed rulemaking citation | Final rulemaking citation |
|---|---|
| § 250.1900 Must I have a SEMS program? | § 250.1900 Must I have a SEMS program? |
| § 250.1901 What is the goal of my SEMS program? | § 250.1901 What is the goal of my SEMS program? |
| § 250.1902 When must I comply with the regulations in this subpart? | § 250.1900(a). Must I have a SEMS program? |

| Proposed rulemaking citation | Final rulemaking citation |
|---|--|
| § 250.1903 May I use an industry standard to develop my SEMS program? | Removed. |
| § 250.1904 What are my general responsibilities for SEMS? | § 250.1909 What is management's general responsibilities for the SEMS program? |
| § 250.1905 What criteria for Hazards Analyses must my SEMS program meet? | § 250.1911 |
| § 250.1906 What criteria for Operating Procedures must my SEMS program meet? | § 250.1913 |
| § 250.1907 What criteria for Mechanical Integrity must my SEMS program meet? | § 250.1916 |
| § 250.1908 What criteria for Management of Change must my SEMS program meet? | § 250.1912 |
| § 250.1909 What criteria must be documented in my SEMS program for contractor selection? | § 250.1914 What criteria must be documented in my SEMS program for safe work practices and contractor selection? |
| § 250.1910 What are my responsibilities when conducting a SEMS audit? | § 250.1920 |
| § 250.1911 What are my documentation and recordkeeping requirements? | § 250.1928 |
| § 250.1912 What qualifications must an independent third-party or my designated and qualified personnel meet? | § 250.1926 |
| § 250.1913 How will BOEMRE determine if my SEMS program is effective? | § 250.1924 |
| § 250.1914 What happens if BOEMRE finds shortcomings in my SEMS program? | § 250.1927 |
| § 250.1915 What are my responsibilities for submitting OCS performance measure data? | § 250.1929 |
| | <p>[NEW SECTION] § 250.1903 Definitions.</p> <p>[NEW SECTION] § 250.1904 Documents incorporated by reference.</p> <p>[NEW SECTION] § 250.1910 What safety and environmental information is required?</p> <p>[NEW SECTION] § 250.1914 What criteria must be documented in my SEMS program for safe work practices and contractor selection?</p> <p>[NEW SECTION] § 250.1915 What criteria for training must be in my SEMS program?</p> <p>[NEW SECTION] § 250.1917 What criteria for pre-start up review must be in my SEMS program?</p> <p>[NEW SECTION] § 250.1918 What criteria for emergency response and control must be in my SEMS?</p> <p>[NEW SECTION] § 250.1919 What criteria for investigation of incidents must be in my SEMS program?</p> <p>[NEW SECTION] § 250.1925 May BOEMRE direct me to conduct additional audits?</p> |

Appendix 1

Instructions on How To Fill Out Form MMS-131—Performance Measures Data

1. On the line titled, "Company Name(s)," enter the name(s) of the operating company(ies) that are the owners of the data that need to be entered on the remainder of this form.

2. Directly across from your entry on "Company Names," please enter the name of the Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) Region where your operating company(ies) have worked and generated the data to be entered on the remainder of this form.

3. On the line titled, "Operator Code(s)," please enter all the known operator codes for the company name or names that you have entered above.

4. Directly across from your entry on "Operator Codes," please enter the Calendar Year the data to be entered on the remainder of the form was generated.

5. On the line titled, "Contact Name," please enter the name of your chosen contact person. This person should be knowledgeable about the data your company has submitted on this form as they will be

the first person the BOEMRE contacts should the bureau have any questions about the data you have provided.

6. Directly across from your entry on "Contact Name," please input an active, valid e-mail address for your "Contact Name."

7. Enter an active and valid telephone number on the line titled, "Telephone." This telephone number should belong to your "Contact Name."

8. Enter an active and valid fax number on the line titled, "Fax." This fax number should be accessible to your "Contact Name."

9. Enter the date this form was submitted to the BOEMRE on the line titled, "Date Submitted."

10. On line A, in the column labeled, "Production Operations," enter the total number of company employee recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of recordable injuries and illnesses suffered by operating company employees while they were engaged in production operations may be entered here.

11. On line A, in the column labeled, "Drilling** Operations," enter the total number of company employee recordable injuries and illnesses accrued in each of the

four quarters of the calendar year. Only the total number of recordable injuries and illnesses suffered by operating company employees while they were engaged in drilling operations may be entered here.

12. On line A, in the column labeled, "Construction Operations," enter the total number of company employee recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of recordable injuries and illnesses suffered by operating company employees while they were engaged in construction operations may be entered here.

13. On line B, in the column labeled, "Production Operations," enter the total number of contract employee recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of recordable injuries and illnesses suffered by contract employees while they were engaged in production operations may be entered here.

14. On line B, in the column labeled, "Drilling** Operations," enter the total number of contract employee recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of recordable injuries and

illnesses suffered by contract employees while they were engaged in drilling operations may be entered here.

15. On line B, in the column labeled, "Construction Operations," enter the total number of contract employee recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of recordable injuries and illnesses suffered by contract employees while they were engaged in construction operations may be entered here.

16. On line C, in the column labeled, "Production Operations," enter the total number of company employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by operating company employees while they were engaged in production operations may be entered here.

17. On line C, in the column labeled, "Drilling** Operations," enter the total number of company employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by operating company employees while they were engaged in drilling operations may be entered here.

18. On line C, in the column labeled, "Construction Operations," enter the total number of company employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by operating company employees while they were

engaged in construction operations may be entered here.

19. On line D, in the column labeled, "Production Operations," enter the total number of contract employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by contract employees while they were engaged in production operations may be entered here.

20. On line D, in the column labeled, "Drilling** Operations," enter the total number of contract employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by contract employees while they were engaged in drilling operations may be entered here.

21. On line D, in the column labeled, "Construction Operations," enter the total number of contract employee DART recordable injuries and illnesses accrued in each of the four quarters of the calendar year. Only the total number of DART recordable injuries and illnesses suffered by *contract* employees while they were engaged in construction operations may be entered here.

22. On line E, in the column labeled, "Production Operations," enter the total number of hours that operating company employees worked on production operations during each of the four quarters of the calendar year.

23. On line E, in the column labeled, "Drilling** Operations," enter the total number of hours operating company employees worked on drilling operations

during each of the four quarters of the calendar year.

24. On line E, in the column labeled, "Construction Operations," enter the total number of hours that operating company employees worked on construction operations during each of the four quarters of the calendar year.

25. On line F, in the column labeled, "Production Operations," enter the total number of hours that contract employees worked on production operations during each of the four quarters of the calendar year.

26. On line F, in the column labeled, "Drilling** Operations," enter the total number of hours contract employees worked on drilling operations during each of the four quarters of the calendar year.

27. On line F, in the column labeled, "Construction Operations," enter the total number of hours that contract employees worked on construction operations during each of the four quarters of the calendar year.

28. On line G, enter the total number of EPA NPDES non-compliances experienced by the operating company during the calendar year.

29. On line H, for oil spills of less than 1 bbl:

a. Count every occurrence of such a spill individually and tally that sum.

b. On line 1, enter the total number of oil spills less than 1 bbl that you have tallied.

c. For each individual spill, estimate the volume of oil lost.

d. Sum the estimates for each spill and enter the final amount of oil lost (in bbls) on line 2.

BILLING CODE 4310-MR-P

U.S. Department of the Interior
 Bureau of Ocean Energy Management,
 Regulation and Enforcement

OMB Control Number 1010-0186
 OMB Approval Expires 10/31/2013

PERFORMANCE MEASURES DATA

Provide Data on an Annual Basis for the Previous Calendar Year by March 31 of Each Year

Company Name(s) _____ BOEMRE Region _____

Operator Code(s)* _____ Calendar Year _____

Contact Name _____ Email Address _____

Telephone _____ Fax _____ Date _____

| <u>SAFETY</u> | <u>PRODUCTION OPERATIONS</u> | <u>DRILLING** OPERATIONS</u> | <u>CONSTRUCTION OPERATIONS</u> |
|---|---|---|---|
| A. No. of Company Employee Recordable Injuries/Illnesses | 1 st Qtr _____ | _____ | _____ |
| | 2 nd Qtr _____ | _____ | _____ |
| | 3 rd Qtr _____ | _____ | _____ |
| | 4 th Qtr _____ | _____ | _____ |
| B. No. of Contract Employee Recordable Injuries/Illnesses | 1 st Qtr _____ | _____ | _____ |
| | 2 nd Qtr _____ | _____ | _____ |
| | 3 rd Qtr _____ | _____ | _____ |
| | 4 th Qtr _____ | _____ | _____ |
| C. No. of Company Employee DART Injuries/Illnesses*** | 1 st Qtr _____ | _____ | _____ |
| | 2 nd Qtr _____ | _____ | _____ |
| | 3 rd Qtr _____ | _____ | _____ |
| | 4 th Qtr _____ | _____ | _____ |
| D. No. of Contract Employee DART Injuries/Illnesses*** | 1 st Qtr _____ | _____ | _____ |
| | 2 nd Qtr _____ | _____ | _____ |
| | 3 rd Qtr _____ | _____ | _____ |
| | 4 th Qtr _____ | _____ | _____ |

| <u>SAFETY</u> | | <u>PRODUCTION OPERATIONS</u> | <u>DRILLING** OPERATIONS</u> | <u>CONSTRUCTION OPERATIONS</u> |
|-----------------------------------|---------------------|------------------------------|------------------------------|--------------------------------|
| E. Company Employee Hours Worked | 1 st Qtr | _____ | _____ | _____ |
| | 2 nd Qtr | _____ | _____ | _____ |
| | 3 rd Qtr | _____ | _____ | _____ |
| | 4 th Qtr | _____ | _____ | _____ |
| F. Contract Employee Hours Worked | 1 st Qtr | _____ | _____ | _____ |
| | 2 nd Qtr | _____ | _____ | _____ |
| | 3 rd Qtr | _____ | _____ | _____ |
| | 4 th Qtr | _____ | _____ | _____ |

ENVIRONMENT

G. No. of EPA NPDES Noncompliances _____

H. For Oil Spills < 1 bbl

1. No. of Spills _____

2. Total Volume for Spills _____ **bbl**

* Please list all operator codes that these data represent.

** Drilling Operations include Drilling, Workover, and Allied Services.

*** Formerly Lost Time Cases that include Days Away from work, Restricted duty, and Transfer situations.

Paperwork Reduction Act of 1995 (PRA): The PRA (44 U.S.C. 3501 et seq.) requires us to inform you that BOEMRE collects this information to carry out its responsibilities under the OCS Lands Act, as amended. BOEMRE will use the information to evaluate the effectiveness of industry’s continued improvement of safety and environmental management in the OCS. Responses are mandatory. No proprietary data are collected. We estimate the public reporting burden, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information to average 10 hours per response. 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 Office of Management and Budget (OMB) control number. The OMB has approved this collection of information and assigned OMB control number 1010-0186. You may direct comments regarding the burden estimate or any other aspect of this collection of information to the Information Collection Clearance Officer, Mail Stop 5438, Bureau of Ocean Energy Management, Regulation and Enforcement, Department of the Interior, 1849 C Street, NW, Washington, DC 20240.

COMPANY-SPECIFIC DATA COLLECTED UNDER THIS REQUEST IS INTENDED FOR GOVERNMENT USE ONLY

BOEMRE Form MMS-131 (Oct 2013 Replaces previous editions that may not be used.) Page 2 of 2

BILLING CODE 4310-MR-C

After reviewing and discussing the comments, BOEMRE decided to require each offshore operator to develop, implement, maintain, and operate under a SEMS program composed of all elements addressed in API RP 75, Development of a Safety and Environmental Management Program for Offshore Operations and Facilities,

Third Edition, May 2004, Reaffirmed May 2008.

In addition to the SEMS elements, we clarified hazards analysis and expanded recordkeeping and documentation requirements. We are also requiring operators to conduct a JSA for OCS activities identified in their SEMS program. In § 250.1911, we allow the

operator to perform a single hazards analysis for simple and multiple similar facilities. The hazards analysis may apply to all such facilities after verifying that site-specific deviations are addressed in each of the elements of your SEMS program. The hazards analysis section in API RP 75 addresses the job task at the facility level.

Therefore, BOEMRE is requiring JSAs as part of the SEMS program under § 250.1911. A JSA is used to review site-specific detailed job steps and uncover hazards associated with the specific job undertaken. The JSA defines the requirements for identifying, assessing, and controlling personal risks associated with work activities. Operators must complete a JSA prior to performing any activity identified in their SEMS program. The supervisor of the person in charge of the task must approve the JSA prior to the work commencing. The JSA is performed to identify and evaluate hazards of a job/task for the purpose of hazards control or elimination that is currently not addressed in API RP 75, Section 3, Hazards Analysis element.

The decision to require a SEMS program plus the JSA requirements is based on BOEMRE accident panel investigation reports, incident investigation findings, analyses of INC data, performance reviews with operators, and the fact that existing BOEMRE regulations do not address the SEMS elements as a separate and comprehensive approach. Since existing regulations (30 CFR part 250) do not address these elements as a separate and comprehensive approach, it is appropriate to require these SEMS elements. BOEMRE's evaluation of safety information included the following:

Accident Panel Investigation Reports

BOEMRE prepares accident panel investigation reports for major accidents. An analysis of 42 accident panel reports from 2000 through 2009 revealed that many fatalities and injuries occurred while performing routine tasks such as drilling, construction, coiled tubing operations, and crane and other lifting events. In addition, most of these accident panel reports' recommendations related to one of the following four SEMS elements: Hazards Analysis, Management of Change, Operating Procedures, and Mechanical Integrity.

The accident panel reports can be viewed at the following Web site: http://www.gomr.BOEMRE.gov/homepg/offshore/safety/acc_repo/accindex.html.

CONTRIBUTING CAUSES

| BOEMRE report | Hazards analysis | Management of change | Operating procedures | Mechanical integrity | Injury # | Fatality # |
|-----------------|------------------|----------------------|----------------------|----------------------|----------|------------|
| BOEMRE 2009-042 | X | X | X | X | 1 | 1 |
| BOEMRE 2009-028 | X | | X | X | | 1 |
| BOEMRE 2009-018 | X | | X | X | | 1 |
| BOEMRE 2009-008 | X | | | | | 1 |
| BOEMRE 2008-056 | | | | X | | |
| BOEMRE 2008-054 | | | | X | | |
| BOEMRE 2008-053 | | X | | | | |
| BOEMRE 2008-038 | | X | X | | | |
| BOEMRE 2008-016 | X | X | X | | | 1 |
| BOEMRE 2007-058 | X | X | X | | | 1 |
| BOEMRE 2007-045 | X | X | X | | | 1 |
| BOEMRE 2007-037 | X | | X | | | 1 |
| BOEMRE 2006-070 | X | | X | X | | 1 |
| BOEMRE 2006-058 | X | | X | | | |
| BOEMRE 2006-047 | X | | X | | | |
| BOEMRE 2006-039 | | | X | | | |
| BOEMRE 2006-021 | | | X | | | |
| BOEMRE 2006-002 | X | | X | | | 1 |
| BOEMRE 2005-027 | | X | X | X | | |
| BOEMRE 2005-007 | | | X | X | | |
| BOEMRE 2004-078 | X | X | X | | | 1 |
| BOEMRE 2004-075 | X | | X | X | | |
| BOEMRE 2004-048 | | | X | X | | |
| BOEMRE 2004-046 | X | X | X | | 3 | |
| BOEMRE 2004-010 | X | | | | | |
| BOEMRE 2004-004 | X | | | | | 1 |
| BOEMRE 2003-068 | | | X | | | |
| BOEMRE 2003-046 | | | X | | | |
| BOEMRE 2003-023 | | X | | | | |
| BOEMRE 2002-080 | | X | | | | |
| BOEMRE 2002-076 | X | X | | X | | 1 |
| BOEMRE 2002-075 | X | | | | | 1 |
| BOEMRE 2002-062 | | X | | | 2 | 1 |
| BOEMRE 2002-059 | X | | | X | 1 | 1 |
| BOEMRE 2002-040 | | | | X | | |
| BOEMRE 2001-084 | | X | | X | | |
| BOEMRE 2001-045 | | X | | X | | 1 |
| BOEMRE 2001-042 | X | X | | X | | 1 |
| BOEMRE 2001-010 | X | X | | | 1 | |
| BOEMRE 2001-009 | | X | X | | | |
| BOEMRE 2001-005 | X | X | | | | |
| BOEMRE 2000-089 | X | | | X | | 1 |
| Total | 24 | 19 | 23 | 17 | 8 | 19 |

The table shows that the accidents covered by 20 of the 42 panel reports resulted in a combined 27 fatalities and injuries. The analysis done on the accidents identified six contributing causes that are related to the four elements:

1. A lack of communication between the operator and contractor(s);
2. A JSA was not conducted prior to beginning work, or there was a lack of written procedures;
3. An onsite supervisor failed to enforce existing procedures or practices;
4. A lack of written safe work procedural guidelines;
5. Integrity of the facilities and equipment were not maintained according to recommended practices; and
6. Workplace hazards were not identified or corrected.

Some of these accidents could have been minimized or prevented if the operator had implemented a comprehensive SEMS.

Incident Analysis

BOEMRE also studied 1,930 incidents that occurred in OCS waters from 2001 through 2009 to determine if those events were associated with any of the following 4 SEMS elements: Hazards

Analysis, Management of Change, Operating Procedures, and Mechanical Integrity. Although these four elements have been identified by BOEMRE as contributing causes to these events, BOEMRE recognizes the value of the remaining API RP 75 elements as a critical part of a comprehensive safety management program helping to ensure that all elements are addressed completely. The events we reviewed included 44 fatalities, 440 injuries, 19 losses of well control, 23 collisions, 597 fires, 436 pollution events, and 371 crane and other lifting events (e.g., hoists, winches, etc.).

The majority of incidents occurring in the OCS were related to operational and maintenance procedures or human error. These incidents are not addressed by BOEMRE's hardware-oriented compliance inspections. Additionally, of the incidents involving injuries, fires, and pollution on production facilities, only 25 were due to failure of a safety device. The majority of the 1,930 incidents had at least 1 of the following 4 elements as a contributing cause for the event occurring:

| SEMS element | Number of incidents |
|----------------------------|---------------------|
| Hazards Analysis | 412 |
| Management of Change | 203 |
| Operating Procedures | 609 |
| Mechanical Integrity | 726 |

Incidents of Noncompliance (INCs)

BOEMRE inspectors issue three General INCs (G-INCs) that potentially relate to elements within a SEMS. The following summarizes these INCs:

- G-110 (Operations conducted in a safe and workmanlike manner),
- G-111 (Equipment maintained in a safe condition), and
- G-112 (Safety of personnel and all necessary precautions taken to correct and remove any hazards).

BOEMRE issued 4,284 G-INCs during 2003-2009 for drilling and production activities. Of these G-INCs issued, 4,116 (approximately 96 percent) were related to 1 or more of the following 4 SEMS elements:

- Hazards Analysis,
- Management of Change,
- Operating Procedures, and
- Mechanical Integrity.

The following table summarizes the G-INCs written for drilling and production activities:

| G-INCs Issued from 2003-2009 | SEMS elements | Drilling percentage |
|------------------------------|---------------|---------------------|
| Hazards Analysis | 23 | 20 |
| Management of Change | 9 | 9 |
| Operating Procedures | 25 | 18 |
| Mechanical Integrity | 39 | 49 |
| Unrelated | 4 | 4 |

BOEMRE evaluation of accident panel investigations and reports, incident analysis, and INCs indicates that in most cases, accidents can be traced to human error and/or organizational failures. For example, not following maintenance procedures as outlined in the SEMS program, could lead to the failure of critical equipment, which could lead to an accident. For that reason, it is important for operators to ensure that safe and environmentally sound operating practices are followed. Operations are safer when management systematically encourages individuals to be safety conscious, provides adequate resources, fosters safe worksite practices, promotes good housekeeping habits, and assures that workers are properly trained.

This final rule will require operators to have their SEMS program audited by an independent third-party or designated and qualified personnel. All auditors must meet the qualifications as

discussed in this final rule and the audit must be conducted according to the schedule in API RP 75, Section 12, and deficiencies addressed by the designated auditor. A knowledgeable and experienced independent third-party or designated and qualified personnel will audit an operator's SEMS program to determine the extent the operator is complying with their SEMS program. These audits will be conducted in an office environment and in the field, and could cover both a broad range of activities or be focused on a particular area (i.e. records, gas compressors, blowout preventers, or documentation), as appropriate. If the auditor determines that a SEMS program does not meet the requirements in this subpart and API RP 75, the operator must submit a report to BOEMRE within 30 days of the audit completion date. The report must outline the results of the audit including deficiencies identified, a timetable or

schedule for implementing corrections to deficiencies, and the person responsible for correcting each identified deficiency including their job title. BOEMRE will verify that corrective actions have been undertaken and that these actions effectively address the audit findings.

BOEMRE may, at its discretion, evaluate independent third parties or designated and qualified personnel, meet with operators to periodically review the results of SEMS program audits, and conduct announced or unannounced evaluations to assess SEMS program compliance and effectiveness. The operators will be responsible for all costs associated with any independent third-party audit of their SEMS program. BOEMRE would be more likely to participate as an observer in the case where the third-party auditor is the same as the contractor who developed the SEMS program.

This final rule requires operators to verify that their contractors can perform their assigned duties. The operator is responsible for ensuring that *all* contractors and subcontractors have safety policies and procedures in place that support the implementation of the SEMS program and align with the principles of managing safety set forth in API RP 75. The operator must inform contractors of any known hazards on the facility that are related to the contractor's work. This applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on or adjacent to a covered process

In this final rule, BOEMRE will require the operator to document and keep the last two SEMS audits conducted (onshore or offshore) and make them available to BOEMRE upon request. In addition, the operator must keep documentation and records for 2 years (onshore or offshore) including the following:

1. JSAs (must be kept onsite for 30 days, electronic access onsite to the JSA would be sufficient to comply with this requirement).
2. Management of change provisions.
3. Injury/illness log.
4. Evaluations completed on contractors.

These records and documentation must be available to BOEMRE upon request.

In this final rule, BOEMRE will require operators to submit Form MMS-131 on an annual basis, broken down quarterly, reporting the previous calendar year's data, by March 31st. For example, on March 31, 2011, Form MMS-131 must be submitted with data from calendar year 2010. On March 31, 2012, the data submitted will be from calendar year 2011.

Form MMS-131 includes the number of hours worked by company and contract employees (people on the facility) during production, drilling, pipeline, and construction activities (including adding or removing equipment and/or facility modifications). Submitting this information will allow the BOEMRE to publish incident rate information that is more useful and representative of the industry's safety record. The collected hours worked data will support BOEMRE's Government Performance and Results Act (GPRA), the Program Assessment Rating Tool (PART), and the OCS Performance Measures Program.

BOEMRE does not want the SEMS program to be a paperwork exercise conducted solely to meet regulatory requirements. BOEMRE understands that the development and implementation of this type of program may place an additional burden on some OCS operators, in the short term. A SEMS program that includes all API RP 75 elements will benefit operators by integrating safety across all aspects of the operating environment.

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

This final rule is a significant rule, as determined by the Office of Management and Budget (OMB), under Section 3(f)(4) of EO 12866 due to its novel legal and policy issues, and is therefore subject to OMB review.

Regulatory Flexibility Act

While the final rule will affect a substantial number of small entities, it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Small operators that operate under this rule fall under the Small Business Administration's (SBA) North American Industry Classification System (NAICS) codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111, Drilling Oil and Gas Wells. For these NAICS code classifications, a small company is one with fewer than 500 employees. Based on these criteria, an estimated 70 percent (91 operators) of the operators on the OCS are considered small. Therefore, this final rule will affect a substantial number of small entities. This rule will not have a significant economic effect on small operators. Costs related to complying with this regulation are relatively small compared to the costs associated with operating offshore on an annual basis.

Assumptions

BOEMRE made the following assumptions concerning the costs associated with the requirements in the final rulemaking:

- Because of the wide variation in company size, we grouped operators into three classes (High, Moderate, and Low Activity).
- We used the results of 13 years of voluntary SEMS Performance Measures reporting by OCS operators and determined that a minimum 70 of the 130 operators are using SEMS. We

believe that this number is higher based on previous Annual Performance Review Meetings conducted by the BOEMRE where voluntary SEMS was discussed.

- We used actual costs from safety management system vendors for our estimated costs for industry.
- We assumed no new capital costs will be incurred for the estimated 70 operators who are currently using SEMS to comply with this final rule, as their systems are already developed and funds they expend to manage and implement this program should not change significantly. However, we calculated additional costs for compliance with JSAs, documentation, maintenance, and recordkeeping requirements.
- The estimated cost for the 60 remaining operators to implement, develop, and manage the SEMS program is based on the operator having an Internet-based system, which is the most common approach used by operators.
- The cost for auditing a SEMS program is part of the entire program, per API RP 75, as audits are an integrated part of maintenance of all elements combined, and the time involved cannot be easily separated out.
- Many smaller operators can use a template from a safety management system vendor that will meet their needs for compliance with the final regulation. In most cases, the operators will not need to spend additional money to customize a template for their use.

High, Moderate, and Low Activity Definitions

Oil and gas operators in the OCS vary substantially in size and the degree to which they are engaged in extracting oil from the OCS. The scale of operations for the 130 OCS oil and gas operators ranges from as little as 1 complex to nearly 500 facilities; and from as little as 15,000 barrels of oil equivalent (BOE) annual production to more than 300 Million (MM) BOE annual production. Because of this variation in activity, BOEMRE divides operators into high, moderate, and low activity for measuring performance. We used these size categories to estimate costs associated with developing, managing, and fulfilling reporting requirements for the final SEMS rule. BOEMRE uses the following criteria for categorizing operators:

| | High activity | Moderate activity | Low activity |
|-------------------------|-------------------|--------------------------|--------------|
| Annual Production | >= 10 MMBOE | 1 MMBOE < 10 MMBOE | < 1 MMBOE. |

| | High activity | Moderate activity | Low activity |
|-----------------------------|---------------------------|------------------------------|-------------------|
| In-service components | >= 1,000 components | 100 < 1,000 components | < 100 components. |

Development of SEMS Program

After reviewing the voluntary SEMS submissions received from 1996 to 2009 (OCS Performance Measures Data, Form MMS-131), an average of 70 of 130

operators, or 54 percent, reported having a SEMS-type program in-place. The other 60 operators, or 46 percent, may not have a SEMS program in-place or may have a SEMS program, but are

not participating in the voluntary SEMS program.

The following table shows a breakdown by operator activity category (high, moderate, low):

| Activity category | Number of operators without SEMS | Number of operators with SEMS | Number of operators with partial SEMS | Total number of operators by activity | Percent of operators with SEMS |
|-----------------------------------|----------------------------------|-------------------------------|---------------------------------------|---------------------------------------|--------------------------------|
| High Activity Operators | 0 | 13 | 0 | 13 | 100 |
| Moderate Activity Operators | 12 | 29 | 10 | 41 | 71 |
| Low Activity Operators | 48 | 28 | 12 | 76 | 37 |
| Total | 60 | 70 | 22 | 130 | 54 |

As shown in the table, 54 percent of all OCS operators have a comprehensive and/or partial SEMS program in place. A partial SEMS includes the following elements; Hazard Analysis, Management of Change, Mechanical Integrity, Operating Procedures, Training, Safe Work Practices. At a September 2009 SEMS workshop held in New Orleans, Louisiana, BOEMRE was informed that moderate and low activity operators are implementing a partial SEMS consisting of six elements previously discussed. They will need to address the other seven elements in order to be in compliance with the final rule. All high activity operators, over 70 percent of the moderate activity operators, and almost 40 percent of the low activity operators are using a SEMS program.

Based on information received from consultants and vendors, the cost for an operator to buy a generic SEMS template is approximately \$2,500. If an operator decided to modify the generic SEMS template to make it specific to its use, the cost will be an additional \$10,000. As mentioned in the assumptions, it will not be necessary for many operators to spend the additional \$10,000 to customize a SEMS program.

If the 60 operators without a SEMS program decide to buy a SEMS template, the cost will be \$150,000 (\$2,500 × 60). If all 60 operators needed to modify the generic plan templates for

their specific OCS operations, which is unlikely, it will cost an additional \$600,000 (\$10,000 × 60). The total cost for all 60 operators to buy a template and then modify the template to their philosophy is estimated to be \$750,000 (\$150,000 + \$600,000).

SEMS Implementation

This section provides the estimated cost for industry to implement a SEMS. The following table shows a breakdown of the average number of facilities and components for the 3 operator activity levels:

| Activity category | Average number of Components per Complex | Average number of Complexes |
|-------------------|--|-----------------------------|
| High | 21 | 139 |
| Moderate ... | 15 | 29 |
| Low | 16 | 6 |

We describe the costs for the 60 operators in the moderate and low activity categories that will have to implement a SEMS Program, and all of the costs for the high, moderate, and low activity categories to maintain their SEMS.

High Activity Operators

BOEMRE determined, based on Annual Performance Reviews and voluntary submissions of Form MMS-

131, that all high activity operators already have a SEMS program in place.

Maintenance Costs for a High Activity Operator

The estimated average cost for each high activity operator to maintain their SEMS program is approximately \$1,670,000 a year. The estimated cost for all 13 high activity operators to maintain their SEMS program is \$21,710,000 per year.

| | |
|--------------------------------------|-----------|
| General | \$ 50,000 |
| Safety and Environmental | 75,000 |
| Hazards analysis | 300,000 |
| Management of Change | 150,000 |
| Operating Procedures | 100,000 |
| Safe Work Practices | 125,000 |
| Training | 200,000 |
| Mechanical Integrity | 225,000 |
| Pre-Startup | 125,000 |
| Emergency Response and Control | 175,000 |
| Investigation of Incidents | 95,000 |
| Audits* | 20,000 |
| Records and Documentation ... | 30,000 |

Total \$1,670,000

* audits are conducted every 3 years at an estimated cost of \$60,000 per audit (\$60,000/3 = \$20,000 per year).

Moderate Activity Operators

BOEMRE calculated the cost for a moderate activity operator to implement and manage a SEMS program based on the 13 SEMS elements, as follows:

IMPLEMENTATION COSTS FOR A MODERATE ACTIVITY OPERATOR

| Element | Basis | Estimated cost |
|---------------|---|--|
| General | The General section includes implementation, planning and management review and approval of the SEMS Program. | \$18,000 per year (includes the year to implement SEMS). This also includes data collection, analysis, report development, and cost of meetings. |

IMPLEMENTATION COSTS FOR A MODERATE ACTIVITY OPERATOR—Continued

| Element | Basis | Estimated cost |
|---------------------------------------|---|--|
| Safety and Environmental Information. | This section outlines the minimum safety and environmental information needed for any facility, such as design data on facility process (e.g., flow diagrams) and mechanical components (e.g., piping and instrument diagrams). The information is used to perform a hazards analysis. | \$22,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, and documentation update of the design data on the facility process and mechanical components. |
| Hazards Analysis | Operators will need a facility risk assessment for each facility. After the initial facility risk assessments are prepared, the cost will be less because a hazards analysis is required only for changes in the process or the equipment on a facility. The JSA at the task level includes data collection, analysis, and report development. This cost is included in the hazards analysis. | \$102,000 per year (includes the year to implement SEMS). This also includes annual updates. |
| Management of Change (MOC). | The cost is based on one change request per month, but it is also dependent on the complexity of the change—something minor will not cost as much as something more complex. The MOC cost is determined by the physical state of the facilities, the status of technology, and the turnover of personnel. | \$30,000 per year (includes the year to implement SEMS). This also includes MOC data collection, evaluation, and documentation update. |
| Operating Procedures | An operator will need to evaluate the operating procedures of its facility each year. The operating procedure cost is determined by the maintenance of such procedures. For most operators, no formal evaluation is necessary since changes will be identified through the JSA process and managed through the MOC process. | \$20,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, documentation update, and recordkeeping. |
| Safe Work Practices | An operator will need to evaluate its safe work practices each year to minimize safety and environmental risks associated with operations. Safe work practices should address all personnel. | \$28,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, inspection report development, and inspection plan update. |
| Training | An operator will need to develop provisions for ensuring that its employees and their supervisors are taught how to conduct operations safely, to recognize unsafe methods of operations, and to identify potential environmental and safety hazards. | \$30,000 per year (includes the year to implement SEMS). This also includes job description review, training program development, and tracking of training and maintenance of training records. The cost of training is not included in this assessment, only the cost of managing the program. Well control and production safety training is implemented following the enforcement of subpart O. |
| Mechanical Integrity | Based on the assumption that mechanical integrity is achieved through preventive maintenance. The preventive maintenance program is defined prior to the commissioning of the facility. We did not include the cost of maintenance in this assessment, only the cost of managing the program. | \$40,000 per year (includes the year to implement SEMS). This includes the quality assurance inspection plan, evaluation of schedule appropriateness, communication of maintenance program, salaries, maintenance and inspection reports, and recordkeeping. |
| Pre-startup Review | An operator will need to include provisions to verify that the facility will function according to design, that personnel have been properly trained, and that safe work practices are in place. | \$25,000 per year (includes the year to implement SEMS). This includes the pre-startup risk register per facility, pre-startup review checklists per facility, records of pre-startup reviews conducted, and evaluation of pre-startup procedures. |
| Emergency Response and Control. | An operator will need to include provisions to require that all emergency response and control plans be in place and ready for immediate implementation. Specific types of plans include, but are not limited to, emergency evacuation and oil spill contingency plans. | \$30,000 per year (includes the year to implement SEMS). This includes initial identification of risks and possible emergencies, development of response requirements and comparison to existing plans, ensuring that drills are performed as planned, and manually tracking and evaluating risk changes. Costs of emergency response and drills are not included in the assessment, only the cost of managing the procedures. |
| Investigation of Incidents | An operator will need to include procedures for investigating all incidents with serious or potentially serious safety and environmental consequences. | \$20,000 per year (includes the year to implement SEMS). This includes incident and near miss registers, collecting data, analyzing, developing, and presentation of reports. Only the cost of preventative measures such as near miss tracking is included in the evaluation. |
| Audits | The operators are required to have an independent third-party or designated and qualified personnel audit of their SEMS program to determine if the program elements were properly implemented and maintained. | \$12,000 every 3 years or \$4,000 per year. |

IMPLEMENTATION COSTS FOR A MODERATE ACTIVITY OPERATOR—Continued

| Element | Basis | Estimated cost |
|---------------------------|---|---|
| Records and Documentation | The operators are required to have documentation that describes the 13 elements of their SEMS program and the interaction between the elements. | \$6,000 per year, based on the requirements of §250.1928 and API RP 75, Section 13. |

The estimated cost for one moderate activity operator to implement SEMS is \$375,000. The estimated cost for the 12 moderate activity operators to implement SEMS is \$4,500,000 (\$375,000 × 12 operators). The itemized cost is:

Implementation Costs for a Moderate Activity Operator

| | |
|--------------------------------------|----------------|
| General | \$18,000 |
| Safety and Environmental | 22,000 |
| Hazards analysis | 102,000 |
| Management of Change | 30,000 |
| Operating Procedures | 20,000 |
| Safe Work Practices | 28,000 |
| Training | 30,000 |
| Mechanical Integrity | 40,000 |
| Pre-Startup | 25,000 |
| Emergency Response and Control | 30,000 |
| Investigation of Incidents | 20,000 |
| Audits | 4,000 |
| Records and Documentation ... | 6,000 |
| Total | 375,000 |

Implementation Costs for a Moderate Activity Operator (Partial SEMS)

The estimated cost for one moderate activity operator with a partial SEMS to

implement a comprehensive SEMS is \$124,000. The estimated cost for the 10 moderate activity operators to implement SEMS is \$1,240,000 (\$124,000 × 10 operators). The itemized cost is:

| | |
|--------------------------------------|----------------|
| General | \$18,000 |
| Safety and Environmental | 22,000 |
| Hazards analysis | 0 |
| Management of Change | 0 |
| Operating Procedures | 0 |
| Safe Work Practices | 0 |
| Training | 0 |
| Mechanical Integrity | 0 |
| Pre-Startup | 25,000 |
| Emergency Response and Control | 30,000 |
| Investigation of Incidents | 20,000 |
| Audits | 3,000 |
| Records and Documentation ... | 6,000 |
| Total | 124,000 |

Maintenance Costs for a Moderate Activity Operator

The estimated average cost for each moderate activity operator to maintain their SEMS program is approximately \$223,000 a year. The estimated cost for the 41 moderate activity operators to

maintain their SEMS program is \$9,143,000 (\$223,000 × 41).

| | |
|--------------------------------------|----------------|
| General | \$3,000 |
| Safety and Environmental | 12,000 |
| Hazards analysis | 34,000 |
| Management of Change | 21,000 |
| Operating Procedures | 17,000 |
| Safe Work Practices | 17,000 |
| Training | 25,000 |
| Mechanical Integrity | 27,000 |
| Pre-Startup | 16,000 |
| Emergency Response and Control | 24,000 |
| Investigation of Incidents | 17,000 |
| Audits * | 4,000 |
| Records and Documentation ... | 6,000 |
| Total | 223,000 |

* Audits are conducted every 3 years at an estimated cost of \$12,000 per audit (\$12,000/3 years = \$4,000 per year).

Low Activity Operators

BOEMRE calculated the cost for a low activity operator to implement and manage a SEMS program based on the 13 SEMS elements, as follows:

IMPLEMENTATION COSTS FOR A LOW ACTIVITY OPERATOR

| Element | Basis | Estimated cost |
|---|--|--|
| General | The General section entails implementation, planning and management review and approval of the SEMS. | \$5,000 per year (includes the year to implement SEMS). This also includes data collection, analysis, report development, and cost of meetings. |
| Safety and Environmental Information | This section outlines the minimum safety and environmental information needed for any facility, such as design data on facility process (e.g., flow diagrams) and mechanical components (e.g., piping and instrument diagrams). The information is used to perform a hazards analysis. | \$8,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, and documentation update of the design data on the facility process and mechanical components. |
| Hazards Analysis | Operators will need to do a facility risk assessment for each facility when the rule is implemented. After the initial facility risk assessments are prepared, the cost will be less because a hazards analysis is required only for changes in the process or the equipment on a facility. The job safety analysis at the task level includes data collection, analysis, and report development. This cost is included in the hazards analysis. | \$25,000 per year (includes the year to implement SEMS). This also includes annual updates. |
| Management of Change (MOC) | Based on one change request per month but the cost is dependent on the complexity of the change. The MOC cost is determined by the physical state of the facilities, the status of technology, and the turnover of personnel. | \$20,000 per year (includes the year to implement SEMS). This also includes MOC data collection, evaluation, and documentation update. |

IMPLEMENTATION COSTS FOR A LOW ACTIVITY OPERATOR—Continued

| Element | Basis | Estimated cost |
|--------------------------------------|---|---|
| Operating Procedures | An operator will need to evaluate the operating procedures of their facility each year. The operating procedure cost is determined by the maintenance of such procedures. For most operators, no formal evaluation is necessary since changes will be identified through the JSA process and managed through the MOC process. | \$10,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, documentation update, and record-keeping. |
| Safe Work Practices | An operator will need to evaluate the safe work practices each year to minimize safety and environmental risks associated with operations. Safe work practices should address all personnel. | \$12,000 per year (includes the year to implement SEMS). This also includes data collection, evaluation, and an inspection report development and inspection plan update. |
| Training | An operator will need to develop provisions for ensuring that their employees and their supervisors be taught how to conduct operations safely, to recognize unsafe methods of operations, and to identify potential environmental and safety hazards. | \$14,000 per year (includes the year to implement SEMS). This also includes job description review, training program development, and tracking of training and maintenance of training records. The cost of training is not included in this assessment, only the cost of managing the program. Training is well implemented following the enforcement of subpart O. |
| Mechanical Integrity | This is based on the assumption that mechanical integrity is achieved through preventive maintenance. The preventive maintenance program is defined prior to the commissioning of the facility. We did not include the cost of maintenance in this assessment, only the cost of managing the program. | \$20,000 per year (includes the year to implement SEMS). This includes the quality assurance inspection plan, evaluation of schedule appropriateness, communication of maintenance program, salaries, maintenance and inspection reports, and recordkeeping. |
| Pre-startup Review | An operator will need to include provisions to verify that the facility will function according to design, that personnel have been properly trained and that safe work practices are in place. | \$8,000 per year (includes the year to implement SEMS). This includes the pre-startup risk register per facility, pre-startup review checklists per facility, records of pre-startup reviews conducted and evaluation of pre-startup procedures. |
| Emergency Response and Control | An operator will need to include provisions to require that all emergency response and control plans be in place and ready for immediate implementation. Specific types of plan include, but are not limited to, emergency evacuation and oil spill contingency plans. | \$15,000 per year (includes the year to implement SEMS). This includes initial identification of risks and possible emergencies, development of response requirements and comparison to existing plans, ensuring that drills are performed as planned, and tracking and evaluating risk changes. Costs of emergency response and drills are not included in the assessment, only the cost of managing the procedures. |
| Investigation of Incidents | An operator will need to include procedures for investigating all incidents with serious or potentially serious safety and environmental consequences. | \$10,000 per year (includes the year to implement SEMS). This includes incident and near miss registers, collecting data, analyzing, and developing and presentation of reports. Only the cost of preventative measures such as near miss tracking is included in the evaluation. |
| Audits | The operators are required to have an independent third-party audit or their designated and qualified personnel of their SEMS program to determine if the program elements were properly implemented and maintained. | \$9,000 every 3 years or \$3,000 per year. |
| Records and Documentation | The operators are required to have documentation that describes the 13 elements of their SEMS program and the interaction between the elements. | \$4,000 per year, based on the requirements of §250.1928 and API RP 75, Section 13. |

The estimated cost for a low activity operator to implement SEMS is \$154,000. The cost for the 48 low activity operators to implement SEMS is \$7,392,000 (\$154,000 × 48 operators). The itemized cost to implement SEMS for a low activity operator is:

Implementation Costs for a Low Activity Operator

| | |
|--------------------------------|---------|
| General | \$5,000 |
| Safety and Environmental | 8,000 |
| Hazards analysis | 25,000 |
| Management of Change | 20,000 |
| Operating Procedures | 10,000 |
| Safe Work Practices | 12,000 |
| Training | 14,000 |

| | |
|--------------------------------------|----------------|
| Mechanical Integrity | 20,000 |
| Pre-Startup | 8,000 |
| Emergency Response and Control | 15,000 |
| Investigation of Incidents | 10,000 |
| Audits | 3,000 |
| Records and Documentation ... | 4,000 |
| Total | 154,000 |

Implementation Costs for a Low Activity Operator (Partial SEMS)

The estimated cost for one low activity operator with a partial SEMS to implement a comprehensive SEMS is \$636,000. The estimated cost for the 12 low activity operators to implement SEMS is \$636,000 (\$53,000 × 12 operators). The itemized cost is:

| | |
|--------------------------------------|---------------|
| General | \$5,000 |
| Safety and Environmental | 8,000 |
| Hazards analysis | 0 |
| Management of Change | 0 |
| Operating Procedures | 0 |
| Safe Work Practices | 0 |
| Training | 0 |
| Mechanical Integrity | 0 |
| Pre-Startup | 8,000 |
| Emergency Response and Control | 15,000 |
| Investigation of Incidents | 10,000 |
| Audits | 3,000 |
| Records and Documentation | 4,000 |
| Total | 53,000 |

Maintenance Cost for a Low Activity Operator

The estimated cost for each low activity operator to maintain their SEMS program is approximately \$77,000 a year. The cost for the 76 low activity operators to maintain SEMS is \$5,852,000.

| | |
|--------------------------------------|---------------|
| General | \$2,000 |
| Safety and Environmental | 3,000 |
| Hazards analysis | 14,000 |
| Management of Change | 7,000 |
| Operating Procedures | 4,000 |
| Safe Work Practices | 5,000 |
| Training | 9,000 |
| Mechanical Integrity | 11,000 |
| Pre-Startup | 5,000 |
| Emergency Response and Control | 7,000 |
| Investigation of Incidents | 3,000 |
| Audits * | 3,000 |
| Records and Documentation | 4,000 |
| Total | 77,000 |

* Audits are conducted every 3 years at an estimated cost of \$9,000 per audit (\$9,000/3 years = \$3,000 per year).

Burden Cost to Submit to BOEMRE

The following are the estimated costs for complying with the submissions to BOEMRE and associated recordkeeping. The burden hours that these costs are based on are addressed in the Paperwork Reduction Act section.

- All JSAs conducted will require a supervisor and/or third-party approval, which will cost \$4,233,050 each year.
- Operators must demonstrate and explain, if required, the policies and procedures included in your SEMS, which will cost \$4,272 each year.

- Make available to BOEMRE evaluations documentation and supporting information, which will cost \$23,140 each year.

- On an annual basis, operators must submit Form MMS-131 (Performance Measures Data) to BOEMRE and maintain a contractor employee injury/illness log in the operation area, which will cost approximately \$115,700.

- Operators must notify the BOEMRE when an operator plans to conduct an audit of its SEMS program in order for BOEMRE to have the opportunity to participate or observe, must submit plans, submit audit reports documenting all findings/conclusions/deficiencies, which will cost approximately \$19,135 each year.

- Recordkeeping and documentation requirements will cost \$57,850 each year.

The total cost for required paperwork being submitted to BOEMRE will be approximately \$4,443,147.

Summary of Annual Costs To Implement and Maintain SEMS

The total cost to implement and maintain SEMS is approximately \$92,910,811. A summary of all the costs are shown in the following table:

SEMS IMPLEMENTATION COSTS

| | Cost* |
|---|-------------------|
| IMPLEMENTATION of your SEMS: | |
| Buy/develop and implement SEMS Plan for operators without a SEMS (60 operators) | \$750,000 |
| Implementation cost | 0 |
| High activity operator cost (already implemented) | 4,500,000 |
| Moderate activity operator cost (\$375,000 × 12) | 1,243,000 |
| Moderate activity operator cost (\$124,000 × 10 operators) (Partial SEMS) | 7,392,000 |
| Low activity operator cost (\$154,000 × 48) | 636,000 |
| Low activity operator cost (\$53,000 × 12) (Partial SEMS) | |
| TOTAL FIRST YEAR COST | 14,521,000 |
| MAINTENANCE of your SEMS: | |
| Maintain SEMS (Annual Cost after Implementation) | |
| High activity operator cost (\$1,670,000 × 13) | 21,710,000 |
| Moderate activity operator cost (\$223,000 × 41) | 9,143,000 |
| Low activity operator cost (\$77,000 × 76) | 5,852,000 |
| ** Conduct required independent third-party audits | 291,000 |
| Paperwork Burden required by BOEMRE (annual cost) | 41,393,811 |
| TOTAL ANNUAL COSTS AFTER IMPLEMENTATION | 78,389,811 |

* Rounded to the nearest \$1,000.

** Required independent audits—approximately 20 percent per operator per category: 3 required audits for high operator (\$20,000 per audit × 3 audits = \$60,000); 8 required audits for moderate operator (\$12,000 per audit × 8 audits = \$96,000); and 15 required audits for low operator (\$9,000 per audit per 15 audits = \$135,000) = 26 required audits per year at a total yearly combined cost of \$291,000.

Benefits of SEMS

The ultimate goal of SEMS is to promote safety and environmental protection during OCS activities. The protection of human life and the environment are the top priorities and objectives of this rule. While it is

difficult to provide absolute quantification of the benefits of the lives saved and risks avoided due to this regulation, the BOEMRE believes that implementation of a comprehensive SEMS program will avoid accidents that could result in injuries, fatalities, and

serious environmental damage based upon BOEMRE's incident analysis. In addition, an increase in a system's level of safety leads to reduced material losses and enhanced productivity.

- Some additional benefits include:
- Avoiding incident investigation costs and operational disruptions.

Improved communication and risk mitigation will prevent many accidents from occurring.

- Reduction of the direct and indirect costs of accidents. Repair costs, damage claims, increased insurance premiums, and civil penalties are a few of the potential economic consequences of an accidental mishap.

- Establishing a marketable safety record. A record of consistently safe operations can attract new business and investment.

- Improved employee morale and productivity. Promoting communication between management and the rest of the organization prevents disenfranchisement and lifts morale.

Again, while it is difficult to quantify with any degree of certainty the human safety and environmental benefits of a comprehensive SEMS program, the financial burden estimated for developing and managing a SEMS program is minor compared to the costs associated with major accidents. For example, in 1987, prior to industry having developed a safety management template for offshore operations, the Mississippi Canyon 311, A (Bourbon), platform in the Gulf of Mexico was tilted to one side by an extensive underground blowout. The cost associated with this incident alone was \$274,000,000. In 1989, a fire associated with a pipeline repair killed 7 people and destroyed a major production facility. A SEMS plan would have implemented several procedures and evaluations that may have prevented these accidents. A SEMS plan is not a guarantee of avoiding all accidents, but BOEMRE believes that requiring a comprehensive SEMS program, that includes all 13 elements, will reduce the likelihood of the types of accidents and incidents discussed in the preamble and will raise the safety awareness of all personnel in the office and field.

The requirement for SEMS will not have a significant economic effect on a substantial number of small entities. Based on voluntary participation in the SEMS program and annual performance reviews, the BOEMRE estimates that over 40 percent of the small entities currently operating on the OCS have implemented some form of a SEMS program. These small entities (28 low activity and 29 moderate activity operators) implemented SEMS because it improved the efficiency and safety of their OCS operations. The cost for each of the remaining small entities to implement (approximately \$154,000) and maintain (approximately \$77,000) SEMS is very small compared to the average annual revenues these entities will generate (\$28,000,000) from the

production of oil and gas. BOEMRE estimated the annual revenue by multiplying the average production for a small entity (700,000 BOE) times a conservative price for a barrel of oil (\$40). These costs should be less for operators that have already addressed this type of information. Therefore, this rulemaking will not have a significant economic effect on a substantial number of small entities.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small businesses. If you wish to comment on the actions of BOEMRE, call 1-888-734-3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act Subtitle E—Congressional Review

This final rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*, also known as the Congressional Review Act). This final rule:

- Will not have an annual effect on the economy of \$100 million or more.
- Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. The requirements will apply to all entities operating on the OCS.

Unfunded Mandates Reform Act of 1995

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year, adjusted for inflation. This final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this final rule does not have significant takings implications. The final rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule does not have federalism implications. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this final rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988.

Specifically, this rule:

- Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

- Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no substantial effects on federally recognized Indian tribes.

Paperwork Reduction Act (PRA)

This rule contains a collection of information that was submitted to the OMB for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The title of the information collection (IC) for this rule is 30 CFR Part 250, Subpart S, Safety and Environmental Management Systems for Outer Continental Shelf Oil and Gas and Sulphur Operations. The OMB approved the collection under Control Number 1010-0186, expiration date 10/31/2013, 465,099 hours, \$12,933,000 non-hour cost burdens. Respondents primarily are an estimated 130 Federal OCS oil, gas, and sulphur lessees and/or operators or other independent third parties. The frequency of response varies, but is primarily annual. Responses to this IC are mandatory. This rulemaking adds a new subpart to the 30 CFR Part 250 regulations. BOEMRE will use the information to: Evaluate the effect of

industry's continued improvement of safety and environmental management of the OCS; develop an industry average that helps to describe how well the offshore oil and gas industry is performing; and judge the reasonableness of company requests for any specific regulatory relief.

BOEMRE will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 522) and its implementing regulations (43 CFR Part 2), and 30 CFR 250.197, Data and information to be made available to the public or for limited inspection.

Section 250.198 lists all of the 30 CFR Part 250 incorporated documents. The section is revised to include the new 30 CFR Part 250, Subpart S, incorporated document added under this regulation.

As stated in the preamble, we received 61 comments, of which 99 percent made some mention of the IC burden. Generally, these commenters said that the IC requirements were too burdensome and that the rule was too prescriptive and should follow API RP 75. BOEMRE is incorporating by reference API RP 75 to replace virtually all of the requirements in the proposed rule. The incorporation of this document allows the operators to address the diversity of operations while developing their SEMS program.

Also, all the commenters remarked that the burden hour estimates were too low; therefore, we increased the burdens to reflect this concern. In response to the comments, BOEMRE has included a new IC requirement in the final rule, adjusted hour burdens, and non-hour cost burdens as follows:

a. In §§ 250.1900–250.1929 under Operator Activity in the proposed rule, the burden hours were increased.

1. High Activity operator burden is increased from the proposed rule due to incorporating API RP 75 in its entirety, which will increase the hour burden (+217,204 hours).

2. Moderate Activity operator burden is increased from the proposed rule due to incorporating API RP 75 in its entirety, which will increase the hour burden and non-hour costs (+64,042 hours; \$2,580,000).

3. Low Activity operator burden is increased from the proposed rule due to incorporating API RP 75 in its entirety, which will increase the hour burden and non-hour costs (+44,384 hours; \$5,472,000).

b. In § 250.1911(b), the designated person in charge of the activity must have approval to conduct a JSA. This requirement will help determine that all physical requirements, environmental conditions, personal protective

equipment, and safety factors relating to a specific job or task have been identified properly (+47,450 hours).

c. In § 250.1914(d), a contractor employee injury/illness log must be kept in the operation area. This requirement is needed to assist in filling out Form MMS–131; therefore, we consider this burden as part of the form burden. (Current OMB approved burden per form is 8 hours; this rulemaking increases the burden per form by an additional 2 hours per form (+260 hours).

d. In § 250.1924(b), BOEMRE has added necessary requirements pertaining to verification of the accuracy of industry's SEMS documentation (+260 burden hours).

e. In § 250.1925(a) there is a new non-hour cost burden that will require an operator to pay for all costs associated with an BOEMRE directed audit. This cost is based on a potential of 26 BOEMRE directed audits a year (+\$291,000).

f. For clarity purposes, we placed the majority of all the recordkeeping and documentation requirements in one regulatory requirement, § 250.1928. This will help respondents determine their requirements at a glance (+650 hours).

The following table provides a breakdown of the burdens.

| Citation 30 CFR 250 subpart S | Reporting and recordkeeping requirement | Non-hour cost burdens | | |
|-------------------------------|--|---|------------------------------------|---------------------|
| | | Hour burden | Average number of annual responses | Annual burden hours |
| 1900–1929 | High Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75 in its entirety. Make your SEMS available to BOEMRE upon request. As part of your SEMS, you must also develop and implement written JSAs for each OCS activity identified or discussed in your SEMS. <i>NOTE:</i> Based on previous information, High Activity Operators already have a SEMS in place. | 18,708 | 13 operators | 243,204 |
| 1900–1929 | Moderate Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75 in its entirety. Make your SEMS available to BOEMRE upon request. As part of your SEMS, you must also develop and implement written JSAs for each OCS activity identified or discussed in your SEMS. | 2,528 | 41 operators | 103,648 |
| | Moderate Activity Operator Implementation. (One time cost to implement SEMS). | \$375,000 per moderate activity implementation × 12 operators = \$4,500,000 | | |

| Citation 30 CFR 250 subpart S | Reporting and recordkeeping requirement | Non-hour cost burdens | | |
|---------------------------------------|--|---|--|---------------------|
| | | Hour burden | Average number of annual responses | Annual burden hours |
| 1900–1929 | Low Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75 in its entirety. Make your SEMS available to BOEMRE upon request. As part of your SEMS, you must also develop and implement written JSAs for each OCS activity identified or discussed in your SEMS. | 899 | 76 operators | 68,324 |
| | Low Activity Operator Implementation. (One time cost to implement SEMS). | \$154,000 per low activity implementation × 48 operators = \$7,392,000. | | |
| 1900 | Develop and implement a SEMS program (One time implementation cost of SEMS template). | \$2,500 per implementation × 60 operators = \$150,000. | | |
| 1900 | In-house modification (one time implementation cost) of the generic SEMS program to meet needs of specific company. | \$10,000 per implementation × 60 operators = \$600,000. | | |
| 1911(b) | Supervisor approval to conduct a JSA | 10 mins. | 130 operators × 365 days × 6 = 284,700*. | 47,450 |
| 1900(b); 1914(d); 1928(d), (e); 1929. | Submit Form MMS–131. Maintain a contractor employee injury/illness log in the operation area, retain for 2 years, and make available to BOEMRE upon request (this requirement is included in the form burden). Inform contractors of hazards. | 10 | 130 operators ... | 1,300 |
| 1920 | Notify BOEMRE with audit schedule 30 days prior to conducting your audit. | 1 | 130 operators/once every 3 years = 43. | 43 (rounded) |
| 1920(c); 1925(a), (c) | Submit to BOEMRE after completed audit, report of findings and conclusions, including deficiencies and required supporting information/documentation. | 3 | 44 operators | 132 |
| 1920(d) | Submit a copy of your plan that will address deficiencies identified in audit, including a correction schedule with appropriate supporting information. | 4 | 10 submissions | 40 |
| 1924(b); | Make available to BOEMRE upon request, evaluation documentation and supporting information relating to your SEMS. | 2 | 130 operators ... | 260 |
| 1924(c) | Explain and demonstrate your SEMS during site visit if required; provide evidence supporting your SEMS implementation. | 8 | 6 explanations .. | 48 |
| 1925(a) | Pay for all costs associated with BOEMRE directed audit approximately 20 percent per operator per category: 3 required audits for high operator (\$20,000 per audit × 3 audits = \$60,000); 8 required audits for moderate operator (\$12,000 per audit × 8 audits = \$96,000; and 15 required audits for low operator (\$9,000 per audit per 15 audits = \$135,000) = 26 required audits per year at a total yearly combined cost of \$291,000. | 26 BOEMRE directed audits—for a total of = \$291,000. | | |

| Citation 30 CFR 250 subpart S | Reporting and recordkeeping requirement | Non-hour cost burdens | | |
|-------------------------------|---|-----------------------|------------------------------------|---------------------|
| | | Hour burden | Average number of annual responses | Annual burden hours |
| 1928 | (1) Document and keep all SEMS audits for 6 years (at least 2 full audit cycles) at an onshore location, and make available to BOEMRE upon request. (2) JSAs must have documented results in writing and kept onsite for 30 days; retain records for 2 years and make available upon request to BOEMRE. (3) All MOC records (API RP Sec 4) must be documented, dated, and retained for 2 years and make available to BOEMRE upon request. | 5 | 130 operators ... | 650 |
| TOTAL BURDEN | | | 285,469 | 465,099 |
| | | | \$12,933,000 Non-Hour Cost Burdens | |

* We calculated operators conducting six JSAs a day (3 JSAs for each 12 hour shift). Some contractors may perform none for a particular day, whereas others may conduct more than six per day. This estimate is an average.

An agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public may comment, at any time, on the accuracy of the IC burden in this rule and may submit any comments to the Department of the Interior; Bureau of Ocean Energy Management, Regulation and Enforcement; Attention: Regulations and Standards Branch; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170-4817.

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. BOEMRE has analyzed this final rule under the criteria of the National Environmental Policy Act and 516 Departmental Manual 15. This final rule meets the criteria set forth in 43 CFR 46.210 for a Departmental "Categorical Exclusion" in that this rule is " * * * of an administrative, financial, legal, technical, or procedural nature * * * " This rule also meets the criteria set forth in 516 Departmental Manual 15.4(C)(1) for a BOEMRE "Categorical Exclusion" in that its impacts are limited to administrative, economic or technological effects. Further, the BOEMRE has analyzed this rule to determine if it meets any of the extraordinary circumstances that will require an environmental assessment or an environmental impact statement as set forth in 43 CFR 46.215.

Each section and subsection has also been reviewed to ensure that no potentially relevant extraordinary circumstances apply to the proposed action that would warrant the preparation of an environmental assessment or environmental impact

statement. All extraordinary circumstances were considered in accordance with 43 CFR 46.215, but only the following ones are potentially applicable:

a. Have significant impacts on public health or safety.

e. Establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects.

f. Have a direct relationship to other actions with individually insignificant but cumulatively significant environmental effects.

The first extraordinary circumstance does not apply since rule promulgation will not contribute to any significant and adverse impacts on public health and safety. The SEMS program is likely to improve OCS safety, given the available incident data trends and associated 10 years of analysis. The second extraordinary circumstance does not apply since the promulgation of the rule or the eventual implementation of SEMS by operators does not set precedent for future actions or decisions by BOEMRE. The last extraordinary circumstance does not apply since there is no direct relationship between this rulemaking and other actions that could together contribute to cumulatively significant effects.

Most subsections of the rule address strictly administrative, technical, and/or procedural matters. Specific examples include definitions of terminology, scope and timing of documentation, recordkeeping, and transfer of information, and general descriptions of what is to be included in written procedures. The rule does not create the potential for environmental effects as a result of new technologies, technology configurations, or technological procedures as such measures are not

part of the rule. For aspects of the rule dealing with mechanical integrity and inspections, the requirements are procedural and technical as the rule covers the content of the written procedures. While the rule identifies the requirement, it allows the operator to choose the means to accomplish the end as long as it is consistent with the SEMS requirements.

Other subsections require activities in addition to administrative tasks, advance planning and procedural documentation, such as training and emergency response drills and corrective procedural actions that address human errors identified in investigations. These requirements are also considered procedural in nature since the subsections describe general and ordered steps that operators must undertake to have and maintain a compliant SEMS program. Subsections that require training or drilling of personnel are procedural in that they target the cognitive skills and knowledge of personnel (e.g., 250.1915(b)) and/or clarify the purpose and/or scope of training (e.g., 250.1918(c)). For example, in 30 CFR 250.1918, BOEMRE requires training and drills for personnel to exercise elements in the Emergency Action Plan that focus on response, control, and evacuation procedures and reporting. The principal purpose of this is to ensure retention of and refine the skills, knowledge, and abilities of personnel.

BOEMRE concluded that this rule does not meet any of the criteria for extraordinary circumstances as set forth in 43 CFR 46.215.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106-554, app.

C § 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

List of Subjects in 30 CFR Part 250

Administrative practice and procedure, Continental shelf, Environmental protection, Incorporation by reference, Public Lands—mineral resources, Reporting and recordkeeping requirements.

Dated: October 1, 2010.
Wilma A. Lewis,
Assistant Secretary—Land and Minerals Management.

■ For the reasons stated in the preamble, Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) is amending 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for 30 CFR part 250 continues to read as follows:

Authority: 31 U.S.C. 9701, 43 U.S.C. 1334.

■ 2. Amend § 250.198 by adding new paragraph (h)(80) to read as follows:

§ 250.198 Documents Incorporated by Reference.

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(h) * * *
 (80) API RP 75, Recommended Practice for Development of a Safety and Environmental Management Program for Offshore Operations and Facilities, Third Edition, May 2004, Reaffirmed May 2008, Product No. G07503; incorporated by reference at § 250.1900, § 250.1900(c), § 250.1902(c), § 250.1903, § 250.1909, § 250.1920(a) and (b).

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■ 3. Revise § 250.199(e)(17) to read as follows:

§ 250.199 Paperwork Reduction Act statements—information collection.

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(e) * * *

30 CFR subpart, title and/or BOEMRE form (OMB Control No.)

Reasons for collecting information and how used

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| (17) Subpart S, Safety and Environmental Management Systems (1010–0186), including Form MMS–131, Performance Measures Data. | | | | The SEMS program will describe management commitment to safety and the environment, as well as policies and procedures to assure safety and environmental protection while conducting OCS operations (including those operations conducted by contractor and sub-contractor personnel). The information collected is the form to gather the raw Performance Measures Data relating to risk and number of accidents, injuries, and oil spills during OCS activities. | | |

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■ 4. Add new subpart S to read as follows:

Subpart S—Safety and Environmental Management Systems (SEMS)

- Sec.
- 250.1900 Must I have a SEMS program?
- 250.1901 What is the goal of my SEMS program?
- 250.1902 What must I include in my SEMS program?
- 250.1903 Definitions.
- 250.1904 Documents incorporated by reference
- 250.1905 through 250.1908 [Reserved]
- 250.1909 What is management’s general responsibilities for the SEMS program?
- 250.1910 What safety and environmental information is required?
- 250.1911 What criteria for hazards analyses must my SEMS program meet?
- 250.1912 What criteria for management of change must my SEMS program meet?
- 250.1913 What criteria for operating procedures must my SEMS program meet?
- 250.1914 What criteria must be documented in my SEMS program for safe work practices and contractor selection?
- 250.1915 What criteria for training must be in my SEMS program?
- 250.1916 What criteria for mechanical integrity must my SEMS program meet?

- 250.1917 What criteria for pre-startup review must be in my SEMS program?
- 250.1918 What criteria for emergency response and control must be in my SEMS program?
- 250.1919 What criteria for investigation of incidents must be in my SEMS program?
- 250.1920 What are the auditing requirements for my SEMS program?
- 250.1921 through 250.1923 [RESERVED]
- 250.1924 How will BOEMRE determine if my SEMS program is effective?
- 250.1925 May BOEMRE direct me to conduct additional audits?
- 250.1926 What qualifications must an independent third party or my designated and qualified personnel meet?
- 250.1927 What happens if BOEMRE finds shortcomings in my SEMS program?
- 250.1928 What are my recordkeeping and documentation requirements?
- 250.1929 What are my responsibilities for submitting OCS performance measure data?

§ 250.1900 Must I have a SEMS program?

You must develop, implement, and maintain a safety and environmental management system (SEMS) program. Your SEMS program must address the elements described in § 250.1902, American Petroleum Institute’s Recommended Practice for Development of a Safety and

Environmental Management Program for Offshore Operations and Facilities (API RP 75) (incorporated by reference as specified in § 250.198), and other requirements as identified in this subpart.

(a) You must comply with the provisions of this subpart and have your SEMS program in effect on or before November 15, 2011, except for the submission of Form MMS–131 as required in § 250.1929.

(b) You must submit Form MMS–131 on an annual basis beginning March 31, 2011.

(c) If there are any conflicts between the requirements of this subpart and API RP 75 (incorporated by reference as specified in § 250.198), you must follow the requirements of this subpart.

(d) Nothing in this subpart affects safety or other matters under the jurisdiction of the Coast Guard.

§ 250.1901 What is the goal of my SEMS program?

The goal of your SEMS program is to promote safety and environmental protection by ensuring all personnel aboard a facility are complying with the policies and procedures identified in your SEMS.

(a) To accomplish this goal, you must ensure that your SEMS program identifies, addresses, and manages safety, environmental hazards, and impacts during the design, construction, start-up, operation, inspection, and maintenance of all new and existing facilities, including mobile offshore drilling units (MODU) while under BOEMRE jurisdiction and Department of Interior (DOI) regulated pipelines.

(b) All personnel involved with your SEMS program must be trained to have the skills and knowledge to perform their assigned duties.

§ 250.1902 What must I include in my SEMS program?

You must have a properly documented SEMS program in place and make it available to BOEMRE upon request as required by § 250.1924(b).

(a) Your SEMS program must meet the minimum criteria outlined in this subpart, including the following SEMS program elements:

- (1) General (*see* § 250.1909)
- (2) Safety and Environmental Information (*see* § 250.1910)
- (3) Hazards Analysis (*see* § 250.1911)
- (4) Management of Change (*see* § 250.1912)
- (5) Operating Procedures (*see* § 250.1913)
- (6) Safe Work Practices (*see* § 250.1914)
- (7) Training (*see* § 250.1915)
- (8) Mechanical Integrity (Assurance of Quality and Mechanical Integrity of Critical Equipment) (*see* § 250.1916)
- (9) Pre-startup Review (*see* § 250.1917)
- (10) Emergency Response and Control (*see* § 250.1918)
- (11) Investigation of Incidents (*see* § 250.1919)
- (12) Auditing (Audit of Safety and Environmental Management Program Elements) (*see* §§ 250.1920)
- (13) Recordkeeping (Records and Documentation) and additional BOEMRE requirements (*see* § 250.1928).

(b) You must also include a job safety analysis (JSA) for OCS activities identified or discussed in your SEMS program (*see* § 250.1911(b)).

(c) Your SEMS program must meet or exceed the standards of safety and environmental protection of API RP 75 (incorporated by reference as specified in § 250.198).

§ 250.1903 Definitions.

Definitions listed in this section apply to this subpart and supersede definitions in API RP 75, Appendices D and E (incorporated by reference as specified in § 250.198).

Designated and qualified personnel means employees (not contractors) that

are knowledgeable of your program, and have actual work experience and training in implementing and auditing a SEMS or a similar program in an offshore oil and gas environment.

Personnel means direct employee(s) of the operator and contracted workers who are involved with or affected by specific jobs or tasks.

§ 250.1904 Documents Incorporated by Reference.

The effect of incorporation by reference of a document into the regulations in this part is that the incorporated document is a requirement. When a section in this part incorporates all of a document, you are responsible for complying with the provisions of that entire document, except to the extent that section provides otherwise. If any incorporated document uses the word “should”, it means must for purposes of these regulations.

§§ 250.1905 through 250.1908 [Reserved]

§ 250.1909 What are management's general responsibilities for the SEMS Program?

You, through your management, must require that the program elements discussed in API RP 75 (incorporated by reference as specified in § 250.198) and in this subpart are properly documented and are available at field and office locations, as appropriate for each program element. You, through your management, are responsible for the development, support, continued improvement, and overall success of your SEMS program. Specifically you, through your management, must:

- (a) Establish goals and performance measures, demand accountability for implementation, and provide necessary resources for carrying out an effective SEMS program.
- (b) Appoint management representatives who are responsible for establishing, implementing and maintaining an effective SEMS program.
- (c) Designate specific management representatives who are responsible for reporting to management on the performance of the SEMS program.

(d) At intervals specified in the SEMS program and at least annually, review the SEMS program to determine if it continues to be suitable, adequate and effective (by addressing the possible need for changes to policy, objectives, and other elements of the program in light of program audit results, changing circumstances and the commitment to continual improvement) and document the observations, conclusions and recommendations of that review.

(e) Develop and endorse a written description of your safety and environmental policies and organizational structure that define responsibilities, authorities, and lines of communication required to implement the SEMS program.

(f) Utilize personnel with expertise in identifying safety hazards, environmental impacts, optimizing operations, developing safe work practices, developing training programs and investigating incidents.

(g) Ensure that facilities are designed, constructed, maintained, monitored, and operated in a manner compatible with applicable industry codes, consensus standards, and generally accepted practice as well as in compliance with all applicable governmental regulations.

(h) Ensure that management of safety hazards and environmental impacts is an integral part of the design, construction, maintenance, operation, and monitoring of each facility.

(i) Ensure that suitably trained and qualified personnel are employed to carry out all aspects of the SEMS program.

(j) Ensure that the SEMS program is maintained and kept up to date by means of periodic audits to ensure effective performance.

§ 250.1910 What safety and environmental information is required?

(a) You must require that SEMS program safety and environmental information be developed and maintained for any facility that is subject to the SEMS program.

(b) SEMS program safety and environmental information must include:

(1) Information that provides the basis for implementing all SEMS program elements, including the requirements of hazard analysis (§ 250.1911);

(2) process design information including, as appropriate, a simplified process flow diagram and acceptable upper and lower limits, where applicable, for items such as temperature, pressure, flow and composition; and

(3) mechanical design information including, as appropriate, piping and instrument diagrams; electrical area classifications; equipment arrangement drawings; design basis of the relief system; description of alarm, shutdown, and interlock systems; description of well control systems; and design basis for passive and active fire protection features and systems and emergency evacuation procedures.

§ 250.1911 What criteria for hazards analyses must my SEMS program meet?

You must ensure the development and implementation of a hazards analysis (facility level) and a job safety analysis (operations/task level) for all of your facilities. For this subpart, facilities include all types of offshore structures permanently or temporarily attached to the seabed (i.e., mobile offshore drilling units; floating production systems; floating production, storage and offloading facilities; tension-leg platforms; and spars) used for exploration, development, production, and transportation activities for oil, gas, or sulphur from areas leased in the OCS. Facilities also include DOI regulated pipelines. You must document and maintain current analyses for each operation covered by this section for the life of the operation at the facility. The analyses must be updated when an internal audit is conducted to ensure that it is consistent with the current operations on your facility. Hazards analysis requirements for simple and nearly identical facilities, such as well jackets and single well caissons, may be fulfilled by performing a single hazards analysis which you can apply to all such facilities after you verify that any site specific deviations are addressed in each of the elements of your SEMS program.

(a) Hazards Analysis (facility level). For a hazards analysis (facility level), you must perform an initial hazards analysis on each facility on or before November 15, 2011. The hazards analysis must be appropriate to the complexity of the operation and must identify, evaluate, and manage the hazards involved in the operation.

(1) The hazards analysis must address the following:

- (i) Hazards of the operation;
- (ii) Previous incidents related to the operation you are evaluating, including any incident in which you were issued an Incident of Noncompliance or a civil or criminal penalty;
- (iii) Control technology applicable to the operation your hazards analysis is evaluating; and
- (iv) A qualitative evaluation of the possible safety and health effects on employees, and potential impacts to the human and marine environments, which may result if the control technology fails.

(2) The hazards analysis must be performed by a person(s) with experience in the operations being evaluated. These individuals also need to be experienced in the hazards analysis methodologies being employed.

(3) You should assure that the recommendations in the hazards

analysis are resolved and that the resolution is documented.

(b) Job Safety Analysis (JSA). You must develop and implement a JSA for OCS activities identified or discussed in your SEMS program.

(1) You must keep a copy of the most recent JSA (operations/task level) at the job site and it must be readily accessible to employees.

(2) Your JSA must identify, analyze, and record:

- (i) The steps involved in performing a specific job;
- (ii) the existing or potential safety and health hazards associated with each step; and
- (iii) the recommended action(s)/ procedure(s) that will eliminate or reduce these hazards and the risk of a workplace injury or illness.

(3) The supervisor of the person in charge of the task must approve the JSA prior to the commencement of the work.

§ 250.1912 What criteria for management of change must my SEMS program meet?

(a) You must develop and implement written management of change procedures for modifications associated with the following:

- (1) Equipment,
- (2) Operating procedures,
- (3) Personnel changes (including contractors),
- (4) Materials, and
- (5) Operating conditions.

(b) Management of change procedures do not apply to situations involving replacement in kind (such as, replacement of one component by another component with the same performance capabilities).

(c) You must review all changes prior to their implementation.

(d) The following items must be included in your management of change procedures:

- (1) The technical basis for the change;
- (2) Impact of the change on safety, health, and the coastal and marine environments;
- (3) Necessary time period to implement the change; and
- (4) Management approval procedures for the change.

(e) Employees, including contractors whose job tasks will be affected by a change in the operation, must be informed of, and trained in, the change prior to startup of the process or affected part of the operation; and

(f) If a management of change results in a change in the operating procedures of your SEMS program, such changes must be documented and dated.

§ 250.1913 What criteria for operating procedures must my SEMS program meet?

(a) You must develop and implement written operating procedures that

provide instructions for conducting safe and environmentally sound activities involved in each operation addressed in your SEMS program. These procedures must include the job title and reporting relationship of the person or persons responsible for each of the facility's operating areas and address the following:

- (1) Initial startup;
- (2) Normal operations;
- (3) All emergency operations (including but not limited to medical evacuations, weather-related evacuations and emergency shutdown operations);
- (4) Normal shutdown;
- (5) Startup following a turnaround, or after an emergency shutdown;
- (6) Bypassing and flagging out-of-service equipment;
- (7) Safety and environmental consequences of deviating from your equipment operating limits and steps required to correct or avoid this deviation;

(8) Properties of, and hazards presented by, the chemicals used in the operations;

(9) Precautions you will take to prevent the exposure of chemicals used in your operations to personnel and the environment. The precautions must include control technology, personal protective equipment, and measures to be taken if physical contact or airborne exposure occurs;

(10) Raw materials used in your operations and the quality control procedures you used in purchasing these raw materials;

(11) Control of hazardous chemical inventory; and

(12) Impacts to the human and marine environment identified through your hazards analysis.

(b) Operating procedures must be accessible to all employees involved in the operations.

(c) Operating procedures must be reviewed at the conclusion of specified periods and as often as necessary to assure they reflect current and actual operating practices, including any changes made to your operations.

(d) You must develop and implement safe and environmentally sound work practices for identified hazards during operations and the degree of hazard presented.

(e) Review of and changes to the procedures must be documented and communicated to responsible personnel.

§ 250.1914 What criteria must be documented in my SEMS program for safe work practices and contractor selection?

Your SEMS program must establish and implement safe work practices

designed to minimize the risks associated with operating, maintenance, and modification activities and the handling of materials and substances that could affect safety or the environment. Your SEMS program must also document contractor selection criteria. When selecting a contractor, you must obtain and evaluate information regarding the contractor's safety and environmental performance. Operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of the operator's SEMS program. Operator and contractor must document their agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at the operator's facilities.

(a) A contractor is anyone performing work for the lessee. However, these requirements do not apply to contractors providing domestic services to the lessee or other contractors. Domestic services include janitorial work, food and beverage service, laundry service, housekeeping, and similar activities.

(b) You must document that your contracted employees are knowledgeable and experienced in the work practices necessary to perform their job in a safe and environmentally sound manner. Documentation of each contracted employee's expertise to perform his/her job and a copy of the contractor's safety policies and procedures must be made available to the operator and BOEMRE upon request.

(c) Your SEMS program must include procedures and verification for selecting a contractor as follows:

(1) Your SEMS program must have procedures that verify that contractors are conducting their activities in accordance with your SEMS program.

(2) You are responsible for making certain that contractors have the skills and knowledge to perform their assigned duties and are conducting these activities in accordance with the requirements in your SEMS program.

(3) You must make the results of your verification for selecting contractors available to BOEMRE upon request.

(d) Your SEMS program must include procedures and verification that contractor personnel understand and can perform their assigned duties for activities such as, but not limited to:

- (1) Installation, maintenance, or repair of equipment;
- (2) construction, startup, and operation of your facilities;
- (3) turnaround operations;
- (4) major renovation; or
- (5) specialty work.

(e) You must:

(1) Perform periodic evaluations of the performance of contract employees that verifies they are fulfilling their obligations, and

(2) maintain a contractor employee injury and illness log for 2 years related to the contractor's work in the operation area, and include this information on Form MMS-131.

(f) You must inform your contractors of any known hazards at the facility they are working on including, but not limited to fires, explosions, slips, trips, falls, other injuries, and hazards associated with lifting operations.

(g) You must develop and implement safe work practices to control the presence, entrance, and exit of contract employees in operation areas.

§ 250.1915 What criteria for training must be in my SEMS program?

Your SEMS program must establish and implement a training program so that all personnel are trained to work safely and are aware of environmental considerations offshore, in accordance with their duties and responsibilities. Training must address the operating procedures (§ 250.1913), the safe work practices (§ 250.1914), and the emergency response and control measures (§ 250.1918). You must document the qualifications of your instructors. Your SEMS program must address:

(a) Initial training for the basic well-being of personnel and protection of the environment, and ensure that persons assigned to operate and maintain the facility possess the required knowledge and skills to carry out their duties and responsibilities, including startup and shutdown.

(b) Periodic training to maintain understanding of, and adherence to, the current operating procedures, using periodic drills, to verify adequate retention of the required knowledge and skills.

(c) Communication requirements to ensure that whenever a change is made to operating procedures (§ 250.1913), the safe work practices (§ 250.1914), or the emergency response and control measures (§ 250.1918), personnel will be trained in or otherwise informed of the change before they are expected to operate the facility.

(d) How you will verify that the contractors are trained in the work practices necessary to perform their jobs in a safe and environmentally sound manner, including training on operating procedures (§ 250.1913), the safe work practices (§ 250.1914), or the emergency response and control measures (§ 250.1918).

§ 250.1916 What criteria for mechanical integrity must my SEMS program meet?

You must develop and implement written procedures that provide instructions to ensure the mechanical integrity and safe operation of equipment through inspection, testing, and quality assurance. The purpose of mechanical integrity is to ensure that equipment is fit for service. Your mechanical integrity program must encompass all equipment and systems used to prevent or mitigate uncontrolled releases of hydrocarbons, toxic substances, or other materials that may cause environmental or safety consequences. These procedures must address the following:

(a) The design, procurement, fabrication, installation, calibration, and maintenance of your equipment and systems in accordance with the manufacturer's design and material specifications.

(b) The training of each employee involved in maintaining your equipment and systems so that your employees can implement your mechanical integrity program.

(c) The frequency of inspections and tests of your equipment and systems. The frequency of inspections and tests must be in accordance with BOEMRE regulations and meet the manufacturer's recommendations. Inspections and tests can be performed more frequently if determined to be necessary by prior operating experience.

(d) The documentation of each inspection and test that has been performed on your equipment and systems. This documentation must identify the date of the inspection or test; include the name and position, and the signature of the person who performed the inspection or test; include the serial number or other identifier of the equipment on which the inspection or test was performed; include a description of the inspection or test performed; and the results of the inspection test.

(e) The correction of deficiencies associated with equipment and systems that are outside the manufacturer's recommended limits. Such corrections must be made before further use of the equipment and system.

(f) The installation of new equipment and constructing systems. The procedures must address the application for which they will be used.

(g) The modification of existing equipment and systems. The procedures must ensure that they are modified for the application for which they will be used.

(h) The verification that inspections and tests are being performed. The

procedures must be appropriate to ensure that equipment and systems are installed consistent with design specifications and the manufacturer's instructions.

(i) The assurance that maintenance materials, spare parts, and equipment are suitable for the applications for which they will be used.

§ 250.1917 What criteria for pre-startup review must be in my SEMS program?

Your SEMS program must require that the commissioning process include a pre-startup safety and environmental review for new and significantly modified facilities that are subject to this subpart to confirm that the following criteria are met:

(a) Construction and equipment are in accordance with applicable specifications.

(b) Safety, environmental, operating, maintenance, and emergency procedures are in place and are adequate.

(c) Safety and environmental information is current.

(d) Hazards analysis recommendations have been implemented as appropriate.

(e) Training of operating personnel has been completed.

(f) Programs to address management of change and other elements of this subpart are in place.

(g) Safe work practices are in place.

§ 250.1918 What criteria for emergency response and control must be in my SEMS program?

Your SEMS program must require that emergency response and control plans are in place and are ready for immediate implementation. These plans must be validated by drills carried out in accordance with a schedule defined by the SEMS training program (§ 250.1915). The SEMS emergency response and control plans must include:

(a) Emergency Action Plan that assigns authority and responsibility to the appropriate qualified person(s) at a facility for initiating effective emergency response and control, addressing emergency reporting and response requirements, and complying with all applicable governmental regulations;

(b) Emergency Control Center(s) designated for each facility with access to the Emergency Action Plans, oil spill contingency plan, and other safety and environmental information (§ 250.1910); and

(c) Training and Drills incorporating emergency response and evacuation procedures conducted periodically for all personnel (including contractor's personnel), as required by the SEMS

training program (§ 250.1915). Drills must be based on realistic scenarios conducted periodically to exercise elements contained in the facility or area emergency action plan. An analysis and critique of each drill must be conducted to identify and correct weaknesses.

§ 250.1919 What criteria for investigation of incidents must be in my SEMS program?

To learn from incidents and help prevent similar incidents, your SEMS program must establish procedures for investigation of all incidents with serious safety or environmental consequences and require investigation of incidents that are determined by facility management or BOEMRE to have possessed the potential for serious safety or environmental consequences. Incident investigations must be initiated as promptly as possible, with due regard for the necessity of securing the incident scene and protecting people and the environment. Incident investigations must be conducted by personnel knowledgeable in the process involved, investigation techniques, and other specialties that are relevant or necessary.

(a) The investigation of an incident must address the following:

(1) The nature of the incident;

(2) The factors (human or other) that contributed to the initiation of the incident and its escalation/control; and

(3) Recommended changes identified as a result of the investigation.

(b) A corrective action program must be established based on the findings of the investigation in order to analyze incidents for common root causes. The corrective action program must:

(1) Retain the findings of investigations for use in the next hazard analysis update or audit;

(2) Determine and document the response to each finding to ensure that corrective actions are completed; and

(3) Implement a system whereby conclusions of investigations are distributed to similar facilities and appropriate personnel within their organization.

§ 250.1920 What are the auditing requirements for my SEMS program?

(a) You must have your SEMS program audited by either an independent third-party or your designated and qualified personnel according to the requirements of this subpart and API RP 75, Section 12 (incorporated by reference as specified in § 250.198) within 2 years of the initial implementation of the SEMS program and at least once every 3 years thereafter. The audit must be a

comprehensive audit of all thirteen elements of your SEMS program to evaluate compliance with the requirements of this subpart and API RP 75 to identify areas in which safety and environmental performance needs to be improved.

(b) Your audit plan and procedures must meet or exceed all of the recommendations included in API RP 75 section 12 (incorporated by reference as specified in § 250.198) and include information on how you addressed those recommendations. You must specifically address the following items:

(1) Section 12.1 General.

(2) Section 12.2 Scope.

(3) Section 12.3 Audit Coverage.

(4) Section 12.4 Audit Plan. You must submit your written Audit Plan to BOEMRE at least 30 days before the audit. BOEMRE reserves the right to modify the list of facilities that you propose to audit.

(5) Section 12.5 Audit Frequency, except your audit interval must not exceed 3 years after the 2 year time period for the first audit.

(6) Section 12.6 Audit Team. The audit that you submit to BOEMRE must be conducted by either an independent third party or your designated and qualified personnel. The independent third party or your designated and qualified personnel must meet the requirements in § 250.1926.

(c) You must require your auditor (independent third party or your designated and qualified personnel) to submit an audit report of the findings and conclusions of the audit to BOEMRE within 30 days of the audit completion date. The report must outline the results of the audit, including deficiencies identified.

(d) You must provide the BOEMRE a copy of your plan for addressing the deficiencies identified in your audit within 30 days of completion of the audit. Your plan must address the following:

(1) A proposed schedule to correct the deficiencies identified in the audit. BOEMRE will notify you within 14 days of receipt of your plan if your proposed schedule is not acceptable.

(2) The person responsible for correcting each identified deficiency, including their job title.

(e) BOEMRE may verify that you undertook the corrective actions and that these actions effectively address the audit findings.

§§ 250.1921 through 250.1923 [Reserved]

§ 250.1924 How will BOEMRE determine if my SEMS program is effective?

(a) BOEMRE or its authorized representative may evaluate or visit

your facility to determine whether your SEMS program is in place, addresses all required elements, and is effective in protecting the safety and health of workers, the environment, and preventing incidents. BOEMRE or its authorized representative may evaluate your SEMS program, including documentation of contractors, independent third parties, your designated and qualified personnel, and audit reports, to assess your SEMS program. These evaluations or visits may be random or based upon the OCS lease operator's or contractor's performance.

(b) For the evaluations, you must make the following available to BOEMRE upon request:

- (1) Your SEMS program;
- (2) The qualifications of your independent third-party or your designated and qualified personnel;
- (3) The SEMS audits conducted of your program;
- (4) Documents or information relevant to whether you have addressed and corrected the deficiencies of your audit; and
- (5) Other relevant documents or information.

(c) During the site visit BOEMRE may verify that:

- (1) Personnel are following your SEMS program,
 - (2) You can explain and demonstrate the procedures and policies included in your SEMS program; and
 - (3) You can produce evidence to support the implementation of your SEMS program.
- (d) Representatives from BOEMRE may observe or participate in your SEMS audit. You must notify the BOEMRE at least 30-days prior to conducting your audit as required in § 250.1920, so that BOEMRE may make arrangements to observe or participate in the audit.

§ 250.1925 May BOEMRE direct me to conduct additional audits?

(a) If BOEMRE identifies safety or non-compliance concerns based on the results of our inspections and evaluations, or as a result of an event, BOEMRE may direct you to have an independent third-party audit of your SEMS program, in addition to the regular audit required by § 250.1920, or BOEMRE may conduct an audit.

- (1) If BOEMRE direct you to have an independent third-party audit,
 - (i) You are responsible for all of the costs associated with the audit, and
 - (ii) The independent third-party audit must meet the requirements of

§ 250.1920 of this part and you must ensure that the independent third party submits the findings and conclusions of a BOEMRE-directed audit according to the requirements in § 250.1920 to BOEMRE within 30 days after the audit is completed.

(2) If BOEMRE conducts the audit, BOEMRE will provide a report of the findings and conclusions within 30 days of the audit.

(b) Findings from these audits may result in enforcement actions as identified in § 250.1927.

(c) You must provide the BOEMRE a copy of your plan for addressing the deficiencies identified in the BOEMRE-directed audit within 30 days of completion of the audit as required in § 250.1920.

§ 250.1926 What qualifications must an independent third party or my designated and qualified personnel meet?

(a) You must either choose an independent third-party or your designated and qualified personnel to audit your SEMS program. You must take into account the following qualifications when selecting the third-party or your designated and qualified personnel:

(1) Previous education and experience with SEMS, or similar management related programs.

(2) Technical capabilities of the individual or organization for the specific project.

(3) Ability to perform the independent third-party functions for the specific project considering current commitments.

(4) Previous experience with BOEMRE regulatory requirements and procedures.

(5) Previous education and experience to comprehend and evaluate how the company's offshore activities, raw materials, production methods and equipment, products, byproducts, and business management systems may impact health and safety performance in the workplace.

(b) You must have procedures to avoid conflicts of interest related to the development of your SEMS program and the independent third party auditor and your designated and qualified personnel.

(c) BOEMRE may evaluate the qualifications of the independent third parties or your designated and qualified personnel. This may include an audit of documents and procedures or interviews. BOEMRE may disallow audits by a specific independent third-

party or your designated and qualified personnel if they do not meet the criteria of this section.

§ 250.1927 What happens if BOEMRE finds shortcomings in my SEMS program?

If BOEMRE determines that your SEMS program is not in compliance with this subpart we may initiate one or more of the following enforcement actions:

(a) Issue an Incident(s) of Noncompliance;

(b) Assess civil penalties; or

(c) Initiate probationary or disqualification procedures from serving as an OCS operator.

§ 250.1928 What are my recordkeeping and documentation requirements?

(a) Your SEMS program procedures must ensure that records and documents are maintained for a period of 6 years, except as provided below. You must document and keep all SEMS audits for 6 years and make them available to BOEMRE upon request. You must maintain a copy of all SEMS program documents at an onshore location.

(b) For JSAs, the person in charge of the activity must document the results of the JSA in writing and must ensure that records are kept onsite for 30 days. You must retain these records for 2 years and make them available to BOEMRE upon request.

(c) You must document and date all management of change provisions as specified in § 250.1912. You must retain these records for 2 years and make them available to BOEMRE upon request.

(d) You must keep your injury/illness log for 2 years and make them available to BOEMRE upon request.

(e) You must keep all evaluations completed on contractor's safety policies and procedures for 2 years and make them available to BOEMRE upon request.

(f) You must keep all records in an orderly manner, readily identifiable, retrievable and legible, and include the date of any and all revisions.

§ 250.1929 What are my responsibilities for submitting OCS performance measure data?

You must submit Form MMS-131 on an annual basis by March 31st. The form must be broken down quarterly, reporting the previous calendar year's data.

[FR Doc. 2010-25665 Filed 10-7-10; 4:15 pm]

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Federal Register

**Friday,
October 15, 2010**

Part IV

Department of Health and Human Services

**42 CFR Part 110
Countermeasures Injury Compensation
Program (CICP): Administrative
Implementation, Interim Final Rule; Final
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 110

RIN 0906-AA83

Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to establish the Countermeasures Injury Compensation Program (CICP or Program). The Department of Health and Human Services (HHS) is issuing this interim final rule with request for comments in order to establish administrative policies, procedures, and requirements for the CICP. This Program is designed to provide benefits to certain persons who sustain serious physical injuries or death as a direct result of administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as the direct result of such covered injuries or their health complications. The Secretary is seeking public comments on this interim final rule.

DATES: This regulation is effective on October 15, 2010. Written *one* comments must be submitted on or before December 14, 2010. The Secretary will consider the comments received and will decide whether to amend the current procedures and requirements based on such comments.

ADDRESSES: You may submit comments in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only of these ways, so that no duplicates are received.

1. *Federal eRulemaking Portal.* You may submit comments electronically to <http://www.regulations.gov>. Click on the link "Submit electronic comments on HRSA regulations with an open comment period." Submit your actual comments as an attachment to your message or cover letter. (Attachments should be in Microsoft Word or WordPerfect; however, we prefer Microsoft Word.)

2. *By regular, express or overnight mail.* You may mail written comments to the following address only: Health

Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, Parklawn Building Rm. 14A-11, 5600 Fishers Lane, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *Delivery by hand (in person or by courier).* If you prefer, you may deliver your written comments before the close of the comment period to the same address: Parklawn Building Room 14A-11, 5600 Fishers Lane, Rockville, MD 20857. Please call in advance to schedule your arrival with one of our HRSA Regulations Office staff members at telephone number (301) 443-1785.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, we cannot accept comments by facsimile (FAX) transmission.

In commenting, please refer to file code [HRSA-2010-0006]. Comments received on a timely basis will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this Notice, in Room 14-05 of the Health Resources and Services Administration's offices at 5600 Fishers Lane, Rockville, MD., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (*phone:* 301-443-1785).

FOR FURTHER INFORMATION CONTACT: Dr. Vito Caserta, Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857. Phone calls can be directed to (888) ASK-HRSA (275-4772). This is a toll-free number.

SUPPLEMENTARY INFORMATION:

Background

This regulation administratively establishes the compensation program authorized by the Public Readiness and Emergency Preparedness Act (the PREP Act) which added new authorities under sections 319F-3 and 319F-4 of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 247d-6d, 247d-6e). The PREP Act, which was enacted as part of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006 (Pub. L. 109-148) on December 30, 2005, confers broad liability protections to covered persons and authorizes compensation to eligible individuals who sustain serious physical injuries or deaths as the direct result of the administration or use of a

covered countermeasure for a disease, condition, or threat that the Secretary of Health and Human Services (the Secretary) determines either constitutes a current public health emergency, or there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is identified in a declaration issued by the Secretary under the PREP Act.

Both the liability protections and the compensation authorized under the PREP Act are invoked by declarations issued by the Secretary (hereinafter PREP Act declarations or declarations) (section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(b)). Through the issuance of such PREP Act declarations, the Secretary makes a determination that a disease, condition, or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. In such declarations, the Secretary recommends targeted liability immunity for persons or entities involved in the manufacture, testing, development, distribution, dispensing, administration, and/or use of a covered countermeasure for the disease, threat, or condition specified. Each Secretarial declaration specifies, for each covered countermeasure identified in the declaration: (a) The category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the covered countermeasure; (b) the period or periods during which the liability protections are in effect (for example, from a certain date through a future date, or other descriptions of events that would trigger the application of the liability protections); (c) the population or populations for whom the Secretary recommends the administration or use of the covered countermeasure (for example, the entire population during a pandemic period); and (d) the geographic area or areas for which the liability protections are in effect (*e.g.*, no geographic limitation, a certain region of the United States). In addition, the Secretary can provide whether the liability protections are only available for specified distribution methods (for example, the liability protections shall only be in effect if the countermeasures are obtained through a voluntary means of distribution). The Secretary may change any component of a declaration by amendment.

The Secretary publishes all PREP Act declarations, and amendments to such declarations, in the **Federal Register**. In addition, they are generally posted on

the Department's Web site at <http://www.hhs.gov/disasters/discussion/planners/prepact/> and on the Program's Web site at <http://www.hrsa.gov/countermeasurescomp/>. As of April 2010, the Secretary had published declarations with respect to the following countermeasures: (1) Pandemic influenza vaccines (including, but not limited to the influenza A H1N1 2009 monovalent vaccine which will be hereafter referred to as the 2009 H1N1 vaccine); (2) anthrax countermeasures; (3) botulism countermeasures; (4) the influenza antiviral drugs Tamiflu® and Relenza® when used for pandemic purposes; (5) smallpox countermeasures; (6) acute radiation syndrome countermeasures; (7) pandemic influenza diagnostics, personal respiratory devices, and respiratory support devices; and (8) the influenza antiviral drug peramivir when used to treat pandemic H1N1 2009 influenza (which will be hereafter referred to as 2009 H1N1). Several of these declarations have been amended, some on multiple occasions.

"Covered countermeasure" is a term of art defined in the PREP Act and includes three categories (section 319F-3(i)(1) of the PHS Act (42 U.S.C. 247d-6d(i)(1)). The first category, consisting of "qualified pandemic or epidemic product[s]," is defined in section 319F-3(i)(7) of the PHS Act (42 U.S.C. 247d-6d(i)(7)). This category includes products (drugs, biological products, and devices) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or to limit the harm such pandemic or epidemic might otherwise cause. The category also extends to products used to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a "qualified pandemic or epidemic product." In order to qualify, a drug, biological product, or device must be: (1) Approved or cleared under the Federal Food, Drug, and Cosmetic Act (FFDCA) or licensed under the PHS Act; (2) the subject of research for possible use and subject to an exemption under sections 505(i) or 520(g) of the FFDCA; or (3) covered under an emergency use authorization (in accordance with section 564 of the FFDCA).

The second category includes "security countermeasure[s]." A security countermeasure, defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. 247d-6b(c)(1)(B)), is a drug, biological product, or device that the Secretary determines: (1) Is a priority to diagnose, mitigate, prevent, or treat

harm either from an agent identified as a material threat or from a condition that may result in injuries or deaths and may be caused by administering a drug, biological product, or device against such an agent; (2) is a necessary countermeasure; and (3) is approved or cleared under the FFDCA or licensed under the PHS Act or will likely be approved, cleared or licensed within eight years or is authorized for emergency use under section 564 of the FFDCA.

The final category consists of products subject to emergency use authorizations. This category extends to drugs (as defined in section 201(g)(1) of the FFDCA, 21 U.S.C. 321(g)(1)), biological products (as defined in section 351(i) of the PHS Act (42 U.S.C. 262), or devices (as defined in section 201(h) of the FFDCA, 21 U.S.C. 321(h)) that are authorized for emergency use in accordance with section 564 of the FFDCA.

In order to be eligible for the liability protections of the PREP Act or to receive benefits under the compensation provisions of the PREP Act, a covered countermeasure must meet one of these three categories and must also be identified by the Secretary in a PREP Act declaration. As explained above, the liability protections afforded by the PREP Act are tied to Secretarial declarations. The PREP Act's liability protections are broad, covering, for example, the manufacture, testing, development, distribution, dispensing, administration or use of the designated covered countermeasure (absent willful misconduct as defined in section 319F-3(c)(1) of the PHS Act (42 U.S.C. 247d-6d(c)(1)). The immunity from suit afforded by the PREP Act applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure[s] (section 319F-3(a)(2)(B) of the PHS Act (42 U.S.C. 247d-6d(a)(2)(B))). For more information about the liability protections afforded to covered persons under the PREP Act, questions and answers are available on the Department's Web site at <http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html> and <http://www.hhs.gov/disasters/discussion/planners/prepact/prepact-h1n1.html>.

In addition to establishing the PREP Act's liability protections for covered persons, the PREP Act authorizes the Secretary to establish a program to provide compensation to eligible individuals for certain covered injuries sustained as the direct result of the administration or use of a covered countermeasure identified in a PREP Act declaration. The Secretary delegated the authority to operate the compensation program described in section 319F-4 of the PHS Act (42 U.S.C. 247d-6e) to the Administrator of the Health Resources and Services Administration (HRSA) on November 8, 2006. Pursuant to this delegation of authority, HRSA established and administers the Countermeasures Injury Compensation Program (hereinafter CICIP or Program).

Under the CICIP, certain persons may be eligible for benefits for covered injuries, described below, sustained as a direct result of the administration or use of covered countermeasures. The PREP Act stipulates that the CICIP will follow, with very limited exceptions, the Smallpox Vaccine Injury Compensation Program (SVICP) for eligibility and compensation determinations (section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)). In addition, the elements of compensation are almost identical to those available under the SVICP (section 319F-4(b)(2) of the PHS Act (42 U.S.C. 247d-6e(b)(2)). The SVICP was established under the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA) and its implementing regulations are available at 42 CFR part 102. Specifically, the PREP Act provides that (with limited exceptions) the CICIP is to follow the SEPPA, the SVICP regulations implementing the SEPPA, and such additional or alternate regulations as the Secretary may promulgate for purposes of this section (section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)). The Secretary is issuing this interim final rule under that authority.

As authorized under the PREP Act, the Secretary is herein, at 42 CFR part 110, establishing the procedures and requirements governing the CICIP. As explained below, the Secretary is issuing this regulation as an interim final rule, to be effective on October 15, 2010. However, the Secretary is seeking public comments on these procedures and requirements and may change provisions of this regulation upon review of the comments received.

Summary of the Regulation

Summary of Available Benefits (§ 110.2)

The benefits available under this Program are medical benefits, benefits for lost employment income, and survivor death benefits. Medical benefits are described more fully in § 110.31 and include payment or reimbursement for medical services and items that the Secretary determines are reasonable and necessary to diagnose or treat a covered injury and to diagnose, treat, or prevent its health complications. Benefits for lost employment income are described more fully in § 110.32 and cover lost employment income incurred as a result of a covered injury or its health complications. Death benefits are described in § 110.33 and provide payments to survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury. As described in § 110.33, death benefits are available under standard or alternative calculations depending upon the eligible survivors.

As explained in § 110.2(b), the PREP Act, based upon provisions included in the SEPPA, establishes that the government generally is a secondary payer for benefits available under the Program. For example, death benefits paid under the alternative calculation in § 110.82(c) are secondary to death and disability benefits under the Public Safety Officers' Benefits (PSOB) Program (a program within the United States Department of Justice that provides payments to public safety officers and their survivors, including death benefits for officers killed in the line of duty).

Benefits under the Program usually will only be paid after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits. Requesters generally must provide the names of all other third party payers that have already provided benefits, that are expected to do so in the future, or that may have a legal or contractual obligation to do so. These payers include, but are not limited to: insurance companies, workers' compensation programs, the Federal Employees' Compensation Act (FECA) Program, military treatment facilities (MTFs), the Department of Veterans Affairs, or the PSOB Program. If such a third-party payer has paid for or provided the type of benefits requested under this Program, the Secretary will only pay such benefits in an amount necessary to supplement the payments

already provided so that the requester does not have unreimbursed out-of-pocket expenses. For example, if a requester determined to be eligible for medical benefits incurred \$10,000 in reasonable and necessary medical expenses resulting from a covered injury and the requester's health insurance company (a third-party payer) has paid \$5,000 for the covered medical benefits and services, the Program would reimburse the requester \$5,000 (representing the amount the requester is entitled to under this Program, reduced by the amount paid or payable by third-party payers). As explained later, upon payment of benefits under the Program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

Eligible Requesters (§ 110.10)

There are three categories of eligible requesters under the Program: (1) Injured countermeasure recipients; (2) survivors of deceased injured countermeasure recipients who died as a direct result of the administration or use of a covered countermeasure; and (3) executors or administrators on behalf of the estates of deceased injured countermeasure recipients (regardless of their cause of death).

Injured Countermeasure Recipients

The first category of requesters, an "injured countermeasure recipient" is defined in § 110.3(n) as an individual:

- (1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:
 - (A) Meets the specifications of the pertinent declaration; or
 - (B) Is administered or uses a covered countermeasure in a good faith belief that he or she meets the specifications of the pertinent declaration; and
- (2) Sustained a covered injury as defined in § 110.3(g).
- (3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(A) or (1)(B), any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

Thus, the eligibility requirements for injured countermeasure recipients may vary based on the terms of the PREP Act declaration issued with respect to the

particular covered countermeasure. For example, all of the declarations issued to date, which are subject to change, include specific limitations in Category I, entitled "Covered Countermeasures." The amended PREP Act declaration for pandemic influenza vaccines specifies that the liability immunity afforded under the PREP Act "shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for vaccines against pandemic influenza A viruses with pandemic potential used and administered in accordance with this Declaration, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the pandemic countermeasures following a declaration of an emergency, as defined in section IX below" (74 FR 51153 (Oct. 5, 2009)). This document defines an Authority Having Jurisdiction as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, Tribal, State, or Federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere or authority." *Id.*

Thus, the immunity protections (and the benefits available under the CICP) are contingent upon either requirement (and not necessarily both) being satisfied. With respect to each requester who received a covered countermeasure identified in a declaration with such language, the Secretary will have to consider whether the administration or use of a covered countermeasure met either of the requirements set forth above or whether there was a good faith belief of such at the time of the administration or use in order to determine whether the person identified as an injured countermeasure recipient meets the requirements of § 110.3(n)(1). In the case of 2009 H1N1 vaccines, this inquiry will generally be simple, given that all such vaccines distributed in the United States were purchased under contract by the Federal Government (satisfying the first requirement quoted above).

The amended PREP Act declaration for the influenza antivirals Tamiflu® and Relenza® contains similar limitations to those described above in its section entitled "Covered Countermeasures." Specifically, the amended PREP Act declaration provides that the liability immunity afforded under the PREP Act "shall only be in

effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding involving countermeasures that are used and administered in accordance with this declaration, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasure following a declaration of an emergency, as defined in section IX below” (73 FR 61861 (Oct. 17, 2008), amended by 74 FR 29213 (June 19, 2009)). The declaration, like other PREP Act declarations, goes on to define “the Authority Having Jurisdiction,” and the “Declaration of Emergency.” Many administrations or uses of pandemic influenza antivirals in the current 2009 H1N1 outbreak will certainly meet the first requirement (e.g., antivirals from the Strategic National Stockpile are under Federal contracts). A more complicated analysis may be required with respect to other administrations or uses to determine whether the alternate requirement (the Authority Having Jurisdiction requirement) was satisfied in particular circumstances. In order for the Authority Having Jurisdiction requirement to apply, the authorized activities must follow a declaration of emergency, as defined in the applicable declaration. With respect to the declaration for Tamiflu® and Relenza®, a “Declaration of Emergency” is defined as “[a] declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FFDCA unless such declaration specifies otherwise” (73 FR at 61863, section IX (definitions)). The same declaration defines the “Authority Having Jurisdiction” as “the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.” *Id.* Thus, the Authority Having Jurisdiction can vary depending upon the circumstances. The Secretary, in an amendment to the PREP Act declaration for the influenza antivirals Tamiflu® and Relenza® for pandemic use, shared her determination that the risk of the spread of 2009 H1N1

viruses and resulting disease constitutes a public health emergency (74 FR 29213 (June 19, 2009), amending 73 FR 61861 (Oct. 17, 2008)). Prior to the issuance of the PREP Act Declaration, the Acting Secretary, pursuant to the authority vested in him under section 319 of the Public Health Service Act, 42 U.S.C. 247d, issued a determination that a public health emergency existed nationwide involving H1N1 influenza that affected or has significant potential to affect national security. This determination was subsequently renewed by the current Secretary. Thus, with respect to covered countermeasures used in connection with the 2009 H1N1 virus, the Secretary has issued a declaration of emergency sufficient to invoke the “Authority Having Jurisdiction” requirement in declarations published to date.

Although the Authority Having Jurisdiction requirement was intentionally worded broadly to account for the complexities of our national public health and emergency response systems (in which the Federal Government, States, localities, tribes, and the private sector play important roles), the Secretary wishes to provide some additional guidance to enable individuals who have been administered or used covered countermeasures to assess their potential eligibility for CICIP benefits as injured countermeasure recipients. In the Secretary’s view, activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasure will apply primarily in two contexts. Under the first scenario, authorized activities would include activities associated with the administration or use of covered countermeasures that were prescribed, administered, delivered, distributed, or dispensed by healthcare providers and others specifically authorized to do so under an agreement, memorandum of understanding, standard operating procedure, or other formal arrangement with an Authority Having Jurisdiction following the declaration of an emergency. In this way, the Authority Having Jurisdiction requirement would extend to individuals receiving medical care from private healthcare providers and institutions provided that the provider or institution is charged, through some sort of formal arrangement, by an Authority Having Jurisdiction with carrying out such activities as part of the public sector’s response.

Under the second scenario, activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction would include covered countermeasures administered or used in accordance with the written recommendations of an Authority Having Jurisdiction following the declaration of an emergency. For example, if a local public health agency recommends that all persons with a certain high-risk condition who contract the 2009 H1N1 virus receive a particular course of treatment with an influenza antiviral identified in a PREP Act declaration following the declaration of emergency for the associated disease, then individuals who use such medications based on their doctors’ compliance with such recommendations would qualify as activities authorized by the Authority Having Jurisdiction. Likewise, the Centers for Disease Control and Prevention (CDC) issued interim recommendations for the use of influenza antivirals for pandemic purposes. *See e.g.*, “Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009–2010 Season” (available at <http://www.cdc.gov/H1N1flu/recommendations.htm>). If an individual used an influenza antiviral for pandemic purposes covered by a PREP Act declaration because his or her physician prescribed the covered countermeasure in accordance with the CDC’s recommendations, then such use would meet the Authority Having Jurisdiction requirement because the physician’s actions would constitute activities authorized by the Authority Having Jurisdiction (in this case, the CDC). Given the complexity of the health care delivery system and the numerous and diverse products already identified as covered countermeasures in PREP Act declarations, an analysis of whether particular specifications included in declarations will necessarily be declaration-specific and fact-specific. The Secretary notes that in certain cases, a patient being administered or using a covered countermeasure as a result of a healthcare provider’s independent medical judgment, and not because the patient necessarily falls within a targeted group identified in an Authority Having Jurisdiction’s recommendations, may qualify as an activity authorized by an Authority Having Jurisdiction because recommendations issued by such authorities often take into account the need for healthcare providers to use independent clinical judgment with

respect to the use or administration of covered countermeasures with respect to each patient. The Secretary does not wish to interfere with such independent clinical judgments.

Although this discussion of the Authority Having Jurisdiction requirement used in declarations to date is intended to assist potential requesters with the CICP, whether a particular recipient was administered or used a covered countermeasure in accordance with a particular PREP Act declaration will be dependent on the language included in the pertinent declaration, as well as the specific circumstances involved.

Administrations and Uses in Pregnant Women

Section 110.3(n)(3) addresses certain circumstances in which a pregnant woman is administered or uses a covered countermeasure. This provision applies to women when their administration or use of a covered countermeasure satisfies all of the terms of a PREP Act declaration (or if there was good faith belief of such). Thus, it applies to women who meet the definition of an injured countermeasure recipient under § 110.3(n) themselves, except that the pregnant women need not suffer a covered injury as required by § 110.3(n)(2). As provided for in § 110.3(n)(3), a child can qualify as an injured countermeasure recipient if the child survives birth, and is born with, or later sustains, a covered injury as the direct result of the mother's administration or use of a covered countermeasure during pregnancy. Such a child's eligibility for compensation under the Program is dependent upon the mother being administered, or using, a covered countermeasure under the terms of a declaration (or based on a good faith belief of such) and upon the child sustaining a covered injury as a result (regardless of whether the mother sustained a covered injury). Absent such a clarification, and in light of the breadth of the PREP Act's liability protections (*see e.g.*, section 319F-3(a)(1)-(2)), such a child might be barred from pursuing litigation against a covered person (*e.g.*, a vaccine manufacturer) for an allegedly related injury (absent willful misconduct) without being afforded compensation otherwise available under the CICP. This is not the Secretary's intention.

Eligibility of children for compensation under this Program does not depend upon whether the covered person (*e.g.*, doctor administering the vaccine) or the mother knew that she was pregnant at the time the covered

countermeasure was administered or used.

Other Requesters

The second category of requesters, survivors of a deceased injured countermeasure recipient, is defined in § 110.3(bb) and described in § 110.11. Categories of eligible survivors and the priority of such survivors to receive benefits from the Program are discussed below in relation to § 110.33, which addresses death benefits (the only type of benefit survivors are eligible to receive).

The third category of requesters encompasses the estates of deceased injured countermeasure recipients, through their executors or administrators. These are individuals who are authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law. Estates of deceased injured countermeasure recipients are not eligible for death benefits, but they may be able to receive the medical and/or lost employment income benefits which the injured countermeasure recipient would have been paid by the Program prior to death, but had not received in full during his or her lifetime.

Members of the Uniformed Services and Eligibility for Benefits Under the CICP

Members of the Uniformed Services may be eligible for benefits under the CICP. The term Uniformed Services means the armed forces, the Commissioned Corps of the National Oceanic and Atmospheric Administration and the Commissioned Corps of the Public Health Service. Such individuals are subject to the same eligibility requirements as civilians. The fact that they are members of the military or a Uniformed Service does not preclude them from receiving benefits under the CICP if they are otherwise eligible. However, given that the CICP is the payer of last resort (including after any medical care, lost wages, or other benefits provided by the United States Government or other third-party payers), the amount of benefits available under the CICP may be minimal because of the benefits they are entitled to by virtue of their status as members of the Uniformed Services.

Territorial Limitations

Section 319F-4(b)(1) of the PHS Act provides that CICP benefits are only available to eligible individuals if their covered injury is caused by a covered countermeasure administered or used pursuant to a declaration issued by the Secretary under 42 U.S.C. 247d-6d(b) (or in a good faith belief of such). One

of the provisions that the PREP Act directs the Secretary to establish in each declaration is the "geographic area or areas" in which liability immunity under the Act is in effect "with respect to the administration or use of the [covered] countermeasure" (section 319F-3(b)(2)(D) of the PHS Act (42 U.S.C. 247d-6d(b)(2)(D)). The Secretary has the discretion to specify in a declaration that liability immunity applies "without geographic limitation," and also to determine "whether the declaration applies only to individuals physically present in such areas or also to individuals who have a connection to such areas, which connection is described in the declaration." *Id.* Although each declaration is unique and all are subject to amendment through publication in the **Federal Register**, the PREP Act declarations published to date provide no geographic limitation and generally apply to any populations that use or are administered the countermeasures in accordance with the terms of the declarations. As long as other eligibility requirements are satisfied, CICP benefits may be paid without regard to United States citizenship.

The Secretary's intent is to provide clear guidance to potential requesters injured by the administration or use of a covered countermeasure. Therefore, she has determined that, *solely for the purpose of administering the CICP*, otherwise eligible individuals at American embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed, may be considered for CICP benefits. Individuals not in one of these categories may not be eligible for benefits under the Program.

Survivors (§ 110.11)

Section 110.11 describes the categories of eligible survivors in the event that the injured countermeasure recipient dies. Survivors may be eligible to receive death benefits under the Program if the Secretary determines that the otherwise eligible injured countermeasure recipient sustained a covered injury and died as a direct result of the injury. Thus, if the Secretary determines that the injured countermeasure recipient died of a cause unrelated to the covered injury, survivors are not eligible to receive death benefits (regardless of the seriousness of the covered injury).

With limited exceptions, the CICP follows the requirements of the PSOB Program with respect to the categories of eligible survivors (known in the PSOB Program as beneficiaries) and the order of priority for payments of death benefits. The order of priority for survivors to receive death benefits under the Program is subject to future changes made to the PSOB Program concerning eligible survivors and their priority to receive death benefits.

Currently, the categories of eligible survivors under the PSOB Program are as follows:

(1) Surviving spouses;

(2) Surviving eligible children (as defined in § 110.3(e)). This definition is based on the definition of "child" within the PSOB. Currently, a surviving child is considered eligible under the PSOB Program if he or she is an individual who is a natural, illegitimate, adopted, or posthumous child, or stepchild, of the deceased person and, at the time of that individual's death, is 18 years of age or younger (*i.e.*, has not reached 19th birthday), or between 19 and 22 years of age and a full-time student, or is older than 18 years of age and incapable of self-support because of physical or mental disability. For clarity, § 110.3(e) defines a stepchild, based on the PSOB's definition of a stepchild, and a posthumous child (a child born after the death of a parent).

(3) Individuals designated by the deceased person as the beneficiaries under the deceased person's most recently executed life insurance policy; or

(4) Surviving parents (of deceased children or adults).

Such survivors, as defined under the PSOB Program, are also eligible survivors under this Program.

The PREP Act, following the SEPPA, included two additional categories of survivors under this Program who are not eligible survivors under the PSOB Program:

(5) Legal guardians of deceased minors without surviving parents; and

(6) Surviving dependents who are younger than the age of 18 (have not reached their 18th birthday). This category could include children who also meet the requirements of category 2 above (surviving eligible children). However, it also includes persons who would not qualify as surviving eligible children (for example, a nephew who was supported by the deceased injured countermeasure recipient, but who was not adopted). Persons who satisfy both category 6 and category 2 (surviving eligible children) may be able to choose between death benefits under the

standard calculation and death benefits under the alternative calculation.

As discussed below, special criteria apply to the final category of eligible survivors. Under current practices, in the event that a deceased injured countermeasure recipient is survived by a spouse and eligible children, the spouse will receive 50 percent of the death benefit and the children will divide the remaining 50 percent equally. If there are no surviving eligible children, then the spouse receives the entire benefit; if there is no surviving spouse, then the children divide the benefit in equal shares. In the event that the deceased injured countermeasure recipient is not survived by a spouse or children, the individual designated by the deceased injured countermeasure recipient as the beneficiary under his or her most recently executed life insurance policy receives the death benefit. If there is no life insurance policy or no surviving designated beneficiary under such a policy, the parents, if living, divide the death benefit in equal shares. If none of these categories of survivors exists, the legal guardian of a deceased minor (who was an injured countermeasure recipient) with no living parent will receive the death benefit, if applicable. As explained in § 110.11(b)(5), surviving dependents younger than the age of 18 (category 6 above) have the same priority as surviving eligible children (category 2 above).

Only the legal guardians of persons qualifying both as surviving eligible children (category 2 above) and as dependents younger than the age of 18 (category 6 above) can choose between a proportional death benefit under the standard and the alternative methods of payment for death benefits, described in detail in § 110.82. Survivors eligible under the PSOB Program's categories of survivors (*e.g.*, spouses, parents, certain insurance designees, and surviving eligible children) who do not qualify as dependent minors are only covered under the standard death benefit calculation. Dependents who are minors and who do not qualify under another category of eligible survivors (under the example given above, a nephew who was supported by the deceased injured countermeasure recipient, but never adopted) are only covered by the alternative method of payment. In the event that survivors are eligible for death benefits under the Program, Program staff will be able to assist families concerning the standard and alternative calculation of death benefits once a determination is made concerning eligibility.

Serious Physical Injuries

As set forth in § 110.20(b), and pursuant to section 319F-4(e)(3) of the PHS Act, only serious physical injuries or deaths are covered by the Program (42 U.S.C. 247d-6e(e)(3)). The definition of a serious physical injury included in the liability provisions of the PREP Act apply only to those provisions and to lawsuits pursuing claims of willful misconduct. Congress did not mandate that the same definition apply within the CICP. Under the definition pertaining to the liability provisions of the PREP Act, a serious physical injury is defined as an injury that (a) is life threatening; (b) results in permanent impairment of a body function or permanent damage to a body structure; or (c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (section 319F-3(i)(10) of the PHS Act (42 U.S.C. 247d-6d(i)(10)). Under the CICP, § 110.20 clarifies that physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious physical injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious physical injuries. Hereafter serious physical injuries will be referred to as serious injuries. This includes instances in which there may be no measurable anatomic or structural change in the affected tissue or organ, but there is an abnormal functional change. For example, many psychiatric conditions are caused by abnormal neurotransmitter levels in key portions of the central nervous system. Thus, it is possible that certain serious psychiatric conditions may qualify as serious physical injuries if the psychiatric conditions are a manifestation of a physical biochemical abnormality in neurotransmitter level or type caused by a covered countermeasure. One way of determining that an abnormal physical change in neurotransmitter level is causing the injury would be a clinical challenge that demonstrates a positive clinical response to a medication that is designed to restore the balance of appropriate neurotransmitters necessary for normal function in an injured countermeasure recipient. However, minor injuries do not meet this definition. For example, covered

injuries do not include common and expected skin reactions (such as localized swelling or warmth that is not of sufficient severity to warrant hospitalization and that does not lead to a significant loss of function or disability) or expected minor scarring at the vaccination site (as occurs commonly with smallpox vaccinations).

Unlike under the VICP, the effects of an injury need not last for a certain period of time (or result in inpatient hospitalization or surgical intervention) for it to be considered a serious injury under the CICP. Therefore, some injured countermeasure recipients may be able to show that they sustained a serious injury which resolved within a relatively short time-frame (for example, a person who sustains a serious injury as the direct result of a covered countermeasure which is successfully treated after two weeks of hospitalization).

The Secretary will consider the unique circumstances of each injury claimed and will make determinations on a case-by-case basis as to whether particular injuries can be considered serious injuries.

Injuries Sustained as a Direct Result of a Disease, and Not of a Covered Countermeasure

Section 110.20(e) makes clear that an injury sustained as the direct result of a disease (or health condition or threat to health) for which the Secretary recommended the administration or use of a covered countermeasure in a PREP Act declaration is not a covered injury. Thus, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury. If a covered countermeasure is ineffective in preventing or treating a disease and an individual suffers the disease, an injury resulting from the disease would not be a covered injury because the injury results from the disease and not from the administration or use of the covered countermeasure. Two examples may be illustrative. Under the first example, an individual receives the 2009 H1N1 vaccine and then goes on to develop 2009 H1N1 influenza because the person failed to develop an immune response to the vaccine. Currently, no vaccine achieves 100% efficacy in stimulating a protective immune response in the population. This is sometimes referred to as failure of vaccine efficacy. If a vaccine recipient suffers a serious complication as the result of contracting the circulating 2009 H1N1 virus, and not as the result of the 2009 H1N1 vaccine or another covered

countermeasure, such injury will not qualify as a covered injury because it results from the disease itself and would have occurred even if the vaccine had not been administered. Under a second example, a person suffering from serious complications as a result of contracting the 2009 H1N1 virus is put on a ventilator that qualifies as a covered countermeasure under a PREP Act declaration. The ventilator malfunctions and the individual suffers a serious health injury as a result of the ventilator malfunction. Such an injury may qualify as a covered injury because it would result from the use of a covered countermeasure (a ventilator) and not directly from the underlying 2009 H1N1 disease. In considering whether an injury results from the administration or use of a covered countermeasure, as opposed to the disease itself, the Secretary will evaluate whether the injury directly resulted from a component or a function of the covered countermeasure (in which case, the injury may qualify as a covered injury) as opposed to the disease itself (in which case, the injury cannot qualify as a covered injury even if a covered countermeasure was administered or used, but was ineffective). Some covered countermeasures may contain attenuated live organisms, such as intranasal 2009 H1N1 vaccine or smallpox vaccine. Despite attenuation, serious infections can rarely be caused by these types of countermeasures. A serious injury resulting from this type of infection (as a result of vaccination) in an injured countermeasure recipient could qualify as a covered injury because it would directly result from the administration or use of a covered countermeasure.

With limited exceptions, the PREP Act provides that the CICP's procedures for determining eligibility, whether eligible persons have sustained covered injuries, whether compensation may be available, and the amount of such compensation shall be the same as those authorized by the SEPPA and implemented in the SVICP. One of these exceptions pertains to individuals who were eligible to apply under the SVICP as a "contact case" based on accidental vaccinia inoculation. The PREP Act makes clear that individuals who contract a disease as a result of contact with a person who used or was administered a covered countermeasure (or other close contacts) may not pursue claims under the CICP for any resulting injuries (sections 319F-4(b)(4), (e)(2), and (e)(5) of the PHS Act (42 U.S.C. 247d-6e(b)(4), (e)(2), and (e)(5))). Thus, although it is possible that in some

circumstances, individuals may suffer injuries as a result of diseases contracted after exposure to individuals because of their use or administration of covered countermeasures (for example, a person who contracts vaccinia after close contact with another person who was administered a smallpox vaccine that qualifies as a covered countermeasure), such contacts cannot pursue benefits under the CICP for such injuries. Contracting a disease in such a manner is extremely rare and will generally only be possible with vaccines containing live viruses.

How To Establish a Covered Injury (§ 110.20)

Covered injuries are defined in § 110.3(g) and are set out in Subpart C of this rule. Covered injuries are defined as serious injuries (or deaths) sustained by injured countermeasure recipients that the Secretary determines are either: (1) An injury meeting the requirements of a Countermeasure Injury Table (Table), discussed below; or (2) an injury that is, in fact, the direct result of the administration or use of a covered countermeasure. The latter requirement includes serious aggravations of pre-existing conditions if such aggravations were caused by a covered countermeasure (e.g., a seizure disorder that is proven, to the satisfaction of the Secretary, to have been made significantly more serious as the direct result of the administration or use of the countermeasure). All requesters (including survivors and executors or administrators of the estate of a deceased countermeasure recipient) must demonstrate that an injured countermeasure recipient sustained a covered injury in order to be eligible for any benefits under the CICP.

Table Injuries

Section 110.20(c) discusses Table injuries. As noted above, one way that requesters can demonstrate that they sustained a covered injury is by demonstrating that they sustained an injury listed on a Countermeasure Injury Table (Table) within the time interval set forth on the Table, as set out in Subpart K (§ 110.100 *et seq.*) of this rule. In accordance with the PREP Act (following the SEPPA), an injured countermeasure recipient shall be presumed to have sustained a covered injury as the direct result of the administration of a covered countermeasure if the requester submits sufficient documentation demonstrating that the injured countermeasure recipient sustained an injury included on a Table, with the onset of the first sign or symptom within the time

interval specified on the Table. The injury must also meet the Table's definitions and requirements, which will be described under Subpart K. In such circumstances, the Secretary will presume, solely for purposes of the Program, that the injured countermeasure recipient's injury was caused by the covered countermeasure (absent another cause, as described below). Such a requester need not actually demonstrate that the covered countermeasure caused the underlying injury, only that an injury listed on the Table (and meeting the Table's definition) was sustained and that it first manifested itself within the time interval listed.

In directing the Secretary to establish a Table with such a presumption, Congress did not direct the Secretary to make this presumption conclusive. In the Secretary's view, it would be inconsistent with the purposes of the PREP Act to do so. For this reason, based on her review of the submitted documentation and other relevant evidence, and consistent with the regulations implementing the SVICP, the Secretary may determine that an injury meeting the Table requirements was actually caused by other factors and was not caused by the covered countermeasure (e.g., if the Secretary determined that the medical records demonstrated that an individual's injury of encephalopathy, a type of brain injury, was caused by a car accident that occurred after a covered countermeasure was used, and neither the encephalopathy nor the car accident was caused by the covered countermeasure itself). In these circumstances, which we expect to occur rarely, the Secretary could rebut a Table presumption of causation and decide that the requester not be afforded the presumption of a Table injury.

The Secretary is authorized under the PREP Act to issue Table(s) for each covered countermeasure identified in a PREP Act declaration. According to the PREP Act, the Secretary may only identify such covered injuries, for purposes of inclusion on a Table, in circumstances where the Secretary determines, based on "compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury" (section 319F-4(b)(5)(A) of the PHS Act (42 U.S.C. 247d-6e(b)(5)(A)). The Secretary plans on reviewing the available scientific evidence concerning covered countermeasures identified in PREP Act declarations and to issue such Tables, when appropriate, through rulemaking. In an effort to administratively

implement the Program as soon as possible, the Secretary is not including such Tables within this rulemaking, but should such Tables be issued in the future, she will do so as amendments to this rule.

Non-Table Injuries

Section 110.20(c) discusses non-Table injuries. Certain requesters who are unable to demonstrate a Table injury may still be able to show that they sustained a covered injury. Such requesters may include those who believe that an injury included on a Table was sustained, but who did not meet all the Table requirements (e.g., the onset of the injury did not occur within the required time interval included on the Table) or those whose injuries are not included on a Table. To establish a covered injury in such circumstances, the Secretary must determine that the injury sustained was the direct result of the administration or use of a covered countermeasure. Under the PREP Act, the Secretary may only make such determinations based on compelling, reliable, valid, medical and scientific evidence (section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)). As described in § 110.20(d), requesters with such claims may need to submit sufficient relevant medical documentation or scientific evidence (such as studies published in peer-reviewed medical literature). In evaluating such claims, the Secretary will take into consideration relevant medical and scientific evidence, including relevant medical records. As provided under the PREP Act, this determination is not reviewable by any court (section 319F-4(b)(5)(C) of the PHS Act (42 U.S.C. 247d-6e(b)(5)(C)). Temporal association between administration or use of the covered countermeasure and onset of the injury (i.e., the injury occurs a certain time after the administration or use) is not sufficient, by itself, to prove that an injury is the direct result of a covered countermeasure.

Benefits Available to Different Categories of Requesters (§ 110.30)

An eligible requester who is an injured countermeasure recipient may be eligible to receive medical benefits, benefits for lost employment income, or both, as long as he or she provides the appropriate documentation. For example, such requesters must submit documentation showing that they have incurred unreimbursable, reasonable, and necessary medical expenses as a result of a covered injury or its health complications to receive medical benefits, and documentation showing

that they lost employment income as a result of a covered injury or its health complications for a specified period in order to receive benefits for lost employment income. Such documentation requirements are discussed later in this rule.

An eligible requester who is a survivor of an otherwise eligible deceased injured countermeasure recipient can only receive a death benefit as a survivor, and no other benefits. Such death benefits are only available if the survivors demonstrate to the satisfaction of the Secretary that the death was caused by the covered injury or its health complications.

The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits, benefits for lost employment income, or both if such benefits were accrued, but were not paid in full, during the deceased person's lifetime. Such benefits may be available regardless of the cause of death. However, the estate would not be eligible to receive payments for benefits that were not accrued during the deceased person's lifetime. For example, the estate would not be entitled to benefits for projected lost employment income that the injured countermeasure recipient might have earned if he or she had not died. In addition, the estate would not be eligible for death benefits, as those benefits are only available to survivors.

Medical Benefits—Summary and Calculation (§ 110.31 and § 110.80)

Medical benefits that may be available under the Program are described in § 110.31. Under the PREP Act, the medical benefits that shall be provided have the same elements and shall be in the same amount as those prescribed by section 264 of the PHS Act (the relevant provision of the SEPPA) (42 U.S.C. 239c). They include payment(s) or reimbursement for medical services and medical items that the Secretary determines are reasonable and necessary for the diagnosis or treatment of a covered injury, or for the diagnosis, treatment, or prevention of the injury's direct health complications. Past, current, and expected future medical services and items may be included in medical benefits. The Secretary is authorized to pay for medical services or items in an effort to cure, counteract, or minimize the effects of any covered injury (or its health complications), or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of benefits to an injured countermeasure recipient. As an example, the CICP may purchase a

health insurance policy for an injured countermeasure recipient, which would have the benefit of providing care to the injured countermeasure recipient over the course of years or a lifetime and the attendant benefit of being an efficient use of Federally-appropriated funds (as compared with direct payments for the services and items covered by the purchased health insurance policy).

In making determinations about which medical services and items provided in the past were reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a healthcare provider. In considering benefits for future medical services and items, the Secretary may consider statements by healthcare providers with expertise in the medical issues involved (for example, a statement by a treating neurologist concerning services and items likely to be needed to address neurological issues) concerning those services and items that appear likely to be needed in the future to diagnose or treat the covered injury or its health complications. However, the Secretary is not bound by such statements. In addition, the Secretary may consider whether the services and items are within the standard of care for the injured countermeasure recipient's medical condition.

As set forth in § 110.31(b), for a requester to receive medical benefits for a health complication of a covered injury, the health complication must have resulted from the covered injury or its treatment and must not be more likely due to other factors or conditions. Examples of health complications include ill effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat the covered injury.

As explained in § 110.31(d), if an injured countermeasure recipient dies before filing with, or being fully paid by, the Program, the deceased person's estate may be eligible for benefits for the cost of medical services and/or items accrued during his or her lifetime as a result of the covered injury or its health complications provided such payments and expenses were not paid in full by a third party during the deceased injured countermeasure recipient's lifetime. Because such payments are for medical expenses accrued as a result of a covered injury while the injured countermeasure recipient was alive, the cause of death does not have to be

related to the covered injury for these medical benefits to be paid to the estate.

The calculation of medical benefits is described in § 110.80. There are no caps on medical benefits. However, the Secretary may limit the payment of such benefits to the amounts (costs) she considers reasonable for those services and items that she considers reasonable and necessary. In addition, payment of medical benefits or reimbursement of costs for medical services and items by the Program is secondary to the obligations of any third-party payer, such as the United States (except for payment of benefits under this Program), State or local government entities, private insurance carriers, employers, or any other third-party payers that may have an obligation to pay for or provide medical benefits. Because the Program is a secondary payer, requesters are required to make good faith efforts to pursue medical benefits from their primary payers. For example, the Program will generally not pay for medical benefits that are paid or payable by the injured countermeasure recipient's medical insurance. As explained in § 110.31(c), requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. Further, § 110.2(b) explains that the benefits available under the CICP usually will only be paid after the requester has in good faith attempted to obtain all other available coverage from third-party payers with an obligation to pay for or provide such benefits. Thus, the Secretary has the discretion not to pay medical benefits if a requester has not made such good faith attempts.

When the Secretary has determined that the requester is eligible for medical benefits and the documentation needed to compute the amount is available, she will do the following, consistent with the calculations described in § 110.80:

(1) Determine which medical expenses that have been submitted are reasonable and necessary to diagnose or treat a covered injury or to diagnose, treat, or prevent its health complications.

(2) Compute all those reasonable medical expenses, including medical services and items provided in the past, and anticipated future medical expenses.

(3) Deduct from the computation the total amount paid, or payable, by all other third-party payers.

This will be the basis for the Program's payment. For example: an eligible injured countermeasure recipient incurred \$5,000 in reasonable and necessary medical expenses. If the individual's insurance company paid

\$3,000, and the individual is responsible for the \$2,000 balance (due to deductibles and co-payments), then the Secretary will pay a medical benefit of \$2,000.

As explained elsewhere in this preamble, the Secretary may make a payment of medical benefits and later pursue such a payment from a third-party payer with an obligation to pay for or provide the medical services or items.

Lost Employment Income—Summary and Calculation (§ 110.32 and § 110.81)

Lost employment income benefits that may be available under the Program appear in § 110.32. Under the PREP Act, compensation for lost employment income under this Program shall have the same elements and shall be in the same amount as prescribed by section 265 of the PHS Act (the relevant provision of the SEPPA) (42 U.S.C. 239d). The CICP will provide benefits for lost employment income (secondary to other benefits that may be available to the requester), subject to limitations described in § 110.81(c), based on the number of days of work that the injured person lost as a result of the covered injury or its health complications (including diagnosis and treatment), and supported by the degree of disability or injury, medical and employment records.

These benefits are a percentage of the employment income lost at the time of injury, due to the covered injury or its health complications, and are based on the number of eligible work days for which such income was lost. Employment income means the injured person's gross employment income at the time of injury. Lost work days do not have to be consecutive, and partial days of lost work are included in the calculation. For example, if an individual's work day is eight hours and he or she missed four hours a day for doctors' appointments on two different days, the eight hours of work missed may be considered one total day of lost wages. As described in § 110.32(c), a day in which an individual used paid leave (e.g., sick leave or vacation leave) in order to be paid for lost work will not be considered a day for which employment income was lost and will not be used in calculating benefits for lost employment income. The only exception to this rule is in a case where the injured person reimburses the employer for the wages paid and the employer restores the paid leave taken so it is available for future use, thus putting the injured countermeasure recipient back in the same position as if he or she had not used paid leave on the lost work day. The Secretary has the

discretion to consider the reasonableness of the number of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation, as well as the severity of the covered injury as demonstrated by the medical records, and to consider alternative work schedules in determining the number of work days lost.

Under the PREP Act, following the SEPPA, the Program cannot pay for the first five days of lost employment income resulting from a covered injury or its health complications, unless the injured countermeasure recipient lost employment income for ten or more work days (in which case, all of the lost work days will be included in the calculation). For this reason, if an individual lost a total of four days (or fewer) of employment income as a result of a covered injury, he or she will not be eligible for any benefits for lost employment income. An injured countermeasure recipient will be compensated for ten or more days of work lost if he or she lost employment income for those days as a result of the covered injury (or its health complications). If the number of days of lost employment income due to the covered injury (or its health complications) is fewer than ten, the Secretary will reduce the number of lost work days by five days.

The calculation of benefits for lost employment income is described in § 110.81. The annual cap on benefits for lost employment income is \$50,000. A requester may use documents such as pay slips, earning and leave statements, and other documents concerning the injured individual's salary, to document his or her employment income. Pursuant to the PREP Act (incorporating the SEPPA), the lost employment income benefit terminates once the injured countermeasure recipient reaches the age of 65. Benefits that represent future lost employment income will be adjusted to account for inflation. It is important to note that future lost employment income will be calculated based on an individual's gross employment income at the time the covered injury was sustained (except for the inflation adjustment provided for in this regulation) and will not be based on an individual's anticipated future employment income. The lifetime cap for the lost employment income benefit is equal to the amount of the death benefit available under the PSOB Program in the same fiscal year in which the lifetime cap is reached (currently \$311,810, but subject to change each fiscal year). However, this lifetime

limitation does not apply if the Secretary determines that an individual has a covered injury considered to be a total and permanent disability under section 216(i) of the Social Security Act. For this reason, an injured countermeasure recipient determined by the Secretary to have a permanent and total disability may be eligible to receive up to \$50,000 a year until he or she reaches the age of 65, without regard to the lifetime cap.

As is the case for medical benefits, if an injured countermeasure recipient dies before filing for, or being fully paid, benefits for lost employment income incurred during his or her lifetime as a result of a covered injury or its health complications, the executor or administrator of that person's estate may file for such benefits on behalf of the estate. Because this payment is made for loss of employment income that accrued while the injured person was alive, the death does not have to be related to the covered injury for these benefits to be paid. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure recipient, of death benefits under § 110.82.

Once the Secretary has determined that she has all the information necessary to compute lost employment income, the calculation will be made as follows, as set out in § 110.81:

(1) The Secretary will make a calculation concerning the number of lost work days that are reasonable based on the degree of injury or disability.

(A) If the injured countermeasure recipient lost five days or fewer of employment income, then no benefits for lost employment income will be paid.

(B) If the injured countermeasure recipient lost six to nine days of employment income, then the Secretary will subtract five days from the number of lost work days for which lost employment income can be paid.

(C) If the injured countermeasure recipient lost ten or more days of employment income, then every lost work day will be counted in calculating the lost employment income benefit.

(2) The Secretary will multiply the injured countermeasure recipient's daily gross employment income (including income from self-employment) at the time of the covered injury by the number of lost work days (as computed above). This figure will be adjusted to account for inflation, as appropriate.

(3) The Secretary will compute 75 percent of the lost employment income if the injured countermeasure recipient had one or more dependents (at the time

of the covered injury) or 66 $\frac{2}{3}$ percent of the lost employment income if there were no dependents (at the time of the covered injury). This calculation will serve as the basis for the lost employment income benefit.

(4) The amount of payment will be reduced by any benefit that the requester is entitled to receive from a third-party payer (e.g., a workers' compensation program). However, the Secretary may make a payment of lost employment income and later pursue such a payment from a third-party payer with an obligation to pay for or provide the benefit (e.g., the Secretary can pay a benefit for lost employment income to a requester with a claim pending in a State workers' compensation program, and then has a right to recover such a payment from the employee or the State if its program determines that such a benefit is due the requester).

(5) The payments made will be subject to an annual cap of \$50,000.

(6) The benefits paid in lost employment income will be subject to a lifetime cap, as discussed above, unless the Secretary determines that a requester has a covered injury considered to be a total and permanent disability under section 216(i) of the Social Security Act.

Death Benefits—Summary and Calculation (§ 110.11, § 110.33, and § 110.82)

Certain survivors of injured countermeasure recipients who died as a direct result of a covered injury or its health complications may be eligible for death benefits, as set out in § 110.11 (eligible survivors and their priority to receive death benefits), § 110.33 (general description of death benefits) and § 110.82 (calculation of death benefits).

Under the PREP Act, compensation for death benefits has the same elements and shall be in the same amount as prescribed by section 266 of the PHS Act (the relevant section of the SEPPA) (42 U.S.C. 239e). Thus, in accordance with the PREP Act (incorporating SEPPA), death benefits under the CICP may be available under one of two different calculations: the "standard calculation" or the "alternative calculation." The "standard calculation" is a lump-sum payment to eligible survivors and is described in § 110.82(b). In general, this method is based on the death benefit available under the PSOB Program. The "alternative calculation" is only available to surviving dependents who are younger than the age of 18, as described in § 110.82(c). This method is based upon the deceased person's

employment income at the time of the covered injury.

Filing a Request Package (§ 110.40–§ 102.41)

A Countermeasures Injury Compensation Program Request for Benefits Form (hereinafter “Request Form”) will be available from the Program. In order for a requester to have his or her Request for Benefits reviewed by the Program, the requester must submit, at a minimum, a completed Request Form (or a Letter of Intent to file a Request Form, described below) postmarked within the filing deadlines established by this regulation. If requesters choose to use a commercial carrier such as Federal Express, United Parcel Service, Emery, etc., or a private delivery service, in the absence of a postmark, the date that the Request Form or Request Package is marked as received by the delivery service will be considered the equivalent of a postmark. Requesters must send their Request Forms and all supporting documentation (the Request Package) to the address listed in § 110.41. To avoid any delays in implementing the Program, the Program will not accept Request Forms or Request Packages electronically at this time. However, the Program will publish a notice in the future if electronic filing becomes available. Once the Program assigns a case number to a requester, all related correspondence should reference the assigned case number.

Filing Deadlines (§ 110.42)

Under the PREP Act, the filing deadlines that applied under SEPPA are mandatory with respect to Request Forms filed with this Program. For that reason, injured countermeasure recipients have one year from the date of the administration or use of a covered countermeasure to submit a Request Form (or Letter of Intent to file a Request Form, as described in § 110.42(b)). For covered countermeasures used or administered over a period of time (for example, antibiotics taken daily for seven days), the filing deadline is one year from the latest administration or use associated with the covered injury. For vaccines administered in more than one dose on different dates (for example, 2009 H1N1 vaccines given in two doses one month apart), the filing deadline is one year from the date of the vaccine administration associated with the injury. Because the PREP Act, incorporating SEPPA, refers to requests based on the administration or use of the countermeasure, the filing deadline that applies to Request Forms filed by

injured countermeasure recipients is the same filing deadline that applies to Request Forms filed by the survivors or the representatives of the estates of deceased injured countermeasure recipients. This one-year filing deadline is absolute, regardless of when the first symptoms of the injury occur or when individuals suspect that the injury may have been caused by a covered countermeasure. Likewise, the one-year filing deadline applies to injuries sustained by a child described in section 110.3(n)(3) (a child under certain circumstances whose covered injuries were the direct result of a covered countermeasure’s administration to, or use by, the mother of the child when she was pregnant with that child). The filing deadline for a Request for Benefits to compensate a child qualifying as an injured countermeasure recipient under section 110.3(n)(3) is one year from the date of administration or use of the covered countermeasure during the mother’s pregnancy. Pursuant to statute, the date of the child’s birth, the date the injury is discovered, or the date the injury is diagnosed is not the basis of determining the filing deadline.

This one-year filing deadline does not apply to *amendments* to previously filed Request Forms. As explained later in the discussion of § 110.46, if an injured countermeasure recipient filed a Request Form within the filing deadline and later dies, his or her survivor(s) (or the representative of his or her estate) may later amend the original Request Package outside of the filing deadline (because the original Request Form was timely filed).

As described in § 110.42(b), requesters may meet the Program’s filing deadline by filing a Letter of Intent to file a Request Form within the governing filing deadline. This mechanism is available to ensure that persons with potential claims will have a means of meeting the Program’s filing deadline even if all of the pertinent documents (*e.g.*, administrative regulation, Request Forms and Instructions) are not yet available. The Program previously notified the public of the ability to file Letters of Intent even before the Program’s regulations are published and the Program’s forms and instructions are available. The Program has made this information available on HRSA’s Web site. Thus, if a requester files a Letter of Intent to file within one year of administration or use of the covered countermeasure that is thought to have caused the injury, then the requester has met the filing deadline. The Program has already received several such letters. All requesters who file a Letter

of Intent should file a Request Form as soon as possible after the Request Form becomes available.

As set forth in § 110.42(d), Request Forms (or Letters of Intent) not filed within the governing filing deadline will not be processed, and the requester will not be eligible for any Program benefits.

Section 110.42(e) also provides for “constructive receipt” of Request Forms, at the Secretary’s discretion. When a requester files a legal action with the Federal Government (*e.g.*, a claim filed pursuant to the Federal Tort Claims Act (FTCA) or a petition for compensation with the VICP) that concerns an alleged injury resulting from the administration or use of a covered countermeasure, then the Secretary may consider the filing of such a legal action (whether an administrative action or a lawsuit) to be “constructive receipt” of a Request Form or Letter of Intent filed under the CICIP, for the purposes of determining the filing date. Given the one-year statute of limitations for this Program and the fact that not all potentially eligible persons may be aware of the Program, the Department may offer such constructive receipt in appropriate circumstances to ensure that claims or lawsuits filed concerning injuries or deaths allegedly resulting from CICIP covered countermeasures will be considered by the CICIP. Thus, if an individual files a VICP claim concerning an injury allegedly sustained as the result of a covered countermeasure and such legal action is filed in the United States Court of Federal Claims within one year of its administration or use, the Secretary has the discretion to decide that the claim was “constructively received” by the Government on the date that such action is filed in court. Despite the Secretary’s ability to consider certain submissions as timely filings for the Program relying on such “constructive receipt,” there is no guarantee that the Secretary will follow this approach in particular cases, and potential requesters must file Request Forms (or Letters of Intent) within the appropriate Program filing deadline in order to be assured of timely filing with the Program.

Section 110.42(f) describes an additional filing deadline available to certain requesters with respect to injuries added to Covered Countermeasures Injury Tables. Through this regulation, the Secretary is reserving Subpart K of this part for Covered Countermeasures Injury Tables, described above. In order to publish this regulation as soon as possible, the Secretary will publish such Tables separately. However, because those Tables will later be included in this

regulation and this part, any initial publications of such Tables or subsequent modifications to such Tables will be considered amendments to this regulation. As described in § 110.42(e), in the event that the Secretary issues a new Covered Countermeasure Injury Table, or amends a previously published Table, requesters will have an extended filing deadline based on the effective date of the Table amendment. However, this extended filing deadline will only apply to requesters if the Table amendment enables a person who could not establish a Table injury before the amendment to establish such an injury. As a hypothetical example, if the Secretary amends this regulation in the future by adding a Table for the 2009 H1N1 vaccine and the Secretary includes an associated injury of anaphylaxis, any person who meets the Table requirements for an injury of anaphylaxis after receiving the 2009 H1N1 vaccine (i.e., suffered the injury of anaphylaxis according to any definitions included on the Table, and suffered the onset of the injury within the time frame listed on the Table after the vaccine administration) would have one year from the effective date of the Table change adding the injury of anaphylaxis to file a Request Form. Such an individual will be afforded this alternative filing deadline because this Table change would enable this potential requester to establish a Table injury. For such persons, this alternative filing deadline applies regardless of whether the requesters previously filed a Request Form with the Program. The filing deadline provided under § 110.42(f) is an additional and alternative filing period to the one afforded to all potential requesters under § 110.42(a). Therefore, persons who would be eligible to use the filing deadline described in § 110.42(f) could rely on the deadline provided under § 110.42(a) or § 110.42(f). Depending on the factual circumstances, it is possible that one or the other deadline could provide a potential requester with a longer period in which to file a Request Form. This additional filing deadline is authorized by the PREP Act's incorporation of SEPPA's filing deadlines for Table amendments. We expect that the filing deadline described in § 110.42(f) may make benefits available to individuals who would otherwise be time-barred with respect to injuries for which new scientific evidence becomes available linking a particular covered countermeasure with a particular injury.

It is important to note that the additional filing deadline described in

§ 110.42(f) is only available to persons who are provided with the presumption of causation of a Table injury by virtue of changes made to a Table. Persons who sustained other injuries or who do not meet all of the requirements for such a Table injury (for example, the definition included on the Table, and the time-frame for onset included on the Table) will not be afforded an additional one year filing deadline based on the effective date of the Table change. Because the Table change would not enable such individuals to establish a Table injury, they would be subject to the standard filing deadline described in § 110.42(a).

Deadlines for Submitting Documentation (§ 110.43)

As described above, a requester will meet the filing deadline requirement by submitting a completed and signed Request Form (or Letter of Intent) within the filing deadline set forth in § 110.42, with documentation to follow at a later date. Although the Secretary will accept documentation required to make eligibility determinations (i.e., documentation described in § 110.50 and §§ 110.51, 110.52, and 110.53 depending upon the nature of the Request) at the time the Request Form is filed, requesters need not submit such documentation at that time. Submitting eligibility documentation as soon as possible will enable the Secretary to make a prompt eligibility determination. The documentation necessary to make benefits determinations (i.e., documentation described in §§ 110.60, 110.61, 110.62, and 110.63, depending on the type of benefits sought) need not be filed until a requester has been notified by the Secretary that the requester is eligible for Program benefits. However, the Secretary will accept such documentation if submitted at an earlier date.

After filing a Request Form (or Letter of Intent) within the filing deadline, a requester must update the Request Package to reflect new information as it becomes available. For example, requesters have an obligation to arrange with their healthcare providers to submit copies of medical records as they are generated.

Legal or Personal Representatives of Requesters (§ 110.44)

Requesters do not need to retain the services of lawyers to pursue benefits under this Program. However, as provided in § 110.44(a), requesters may have a legal or personal representative (e.g., lawyer, guardian, family member, or friend) submit the Request Form (or Letter of Intent) and/or Request Package

on their behalf. In certain circumstances, described below, requesters may be required to have a legal or personal representative file on their behalf. All representatives filing on behalf of requesters will be bound by the obligations and documentation requirements that apply to the requester. For example, if this regulation requires a requester to submit his or her medical records, the requester's representative would be required to submit those records on behalf of the requester. If a requester has a legal or personal representative, the Program will generally direct all communications to the representative unless the Program is advised that the representation has stopped. However, as described in § 110.40(a), the Secretary reserves the right to contact the requester directly if necessary (e.g., in circumstances in which the Secretary is unable to contact the representative). The Secretary also reserves the right to contact requesters at a later date to conduct a follow-up survey to help determine improvements in the ability of the Program to meet the needs of requesters.

As described in § 110.44(b), a legally competent requester may use a representative to submit a Request Package on his or her behalf. In such circumstances, the requester must indicate on the Request Form that he or she has authorized the representative to submit the Request Package on his or her behalf.

Requesters who are minors or adults who do not have legal capacity to receive payments (i.e., adults determined to be legally incompetent by a court having jurisdiction) are required to have the assistance of a representative (who does not need to be a lawyer). Representatives of requesters who are minors (excepting emancipated minors), or adults determined by a court not to have legal capacity to receive payments, are required to submit specific documentation, in addition to the documentation generally required of requesters, which is described in § 100.63.

As explained above, although legal representation is permitted, it is not needed for filing for Program benefits. As described in § 110.44(d), the Program will not be responsible for the payment or reimbursement of any fees for the services of legal or personal representatives or for any associated costs. The authorizing statute does not permit the Program to pay any attorney's fees or related costs.

Multiple Survivors (§ 110.45)

If there are multiple survivors, then each survivor may submit Request

Forms separately or the group of survivors may submit one Request Form together. Multiple survivors are not required to file separate supporting documentation; rather, they may submit one complete set of supporting documentation on behalf of all survivors.

Amendments to Request Packages (§ 110.46)

The filing of amendments to previously filed Request Packages is discussed in § 110.46. As explained in § 110.46(a), all requesters may amend their documentation concerning eligibility until the Secretary makes an eligibility determination. After that time, the Secretary will not accept additional documentation concerning eligibility (except amendments filed by survivors or the estates of deceased countermeasure recipients, discussed below).

After the Secretary makes a benefits determination (e.g., determines that no benefits may be awarded because all eligible benefits have been paid by other third party payers, or determines that a requester is entitled to benefits and sets the amount of the award), the determination is final and the Secretary will not accept new benefits documentation regarding that covered injury (except amendments filed by survivors or the estates of deceased countermeasure recipients, discussed below). The Secretary believes that benefits determinations must have finality. The Secretary will do her best to assess the appropriate level of benefits based on the information before her at the time of the benefits determination. In certain circumstances, such determinations may be based on the Secretary's assessment of the likely future needs of a requester. For example, a medical benefits award will be based, in part, on the Secretary's best judgment as to the anticipated future course of an injured countermeasure recipient's illness. Because reopening such benefits decisions would create an unreasonable administrative burden and would prevent finality, the Secretary will not consider new evidence concerning the appropriate level or type of benefits after the benefits determination has been made. If another approach were pursued, the Secretary could be in the position of revisiting benefits every time a requester's medical condition or insurance coverage altered, even slightly. The Program is not in a position to constantly re-evaluate such determinations.

Although new documentation cannot be submitted after a determination has been made, applicants have a right to

seek reconsideration of an unfavorable eligibility or benefits decision (Section 110.90).

Section 110.46(b) addresses amendments filed by requesters who are survivors. If an injured countermeasure recipient filed a Request Package, but later dies, his or her survivors may amend the Request Package by filing a new Request Form. A survivor filing such an amended request will only be entitled to benefits under the Program if the original Request Form (filed by or on behalf of the injured countermeasure recipient, his or her estate, or other survivors) was filed within the applicable one year filing deadline. If such an amendment is filed, all of the documentation submitted with the original Request Package will be considered part of the amended Request Package and the survivor need not resubmit such documentation. If the injured countermeasure recipient (or his or her estate) never filed a Request Package, a Request Form filed by a survivor would be considered the beginning of a new Request Package and not an amendment to a previously filed Request Package. As set forth in § 110.46(b), survivors must file an amendment to a Request Package if there is a change in the eligible survivors (for example, the spouse of an injured countermeasure recipient dies).

Section 110.46(c) addresses amendments filed by the executor or administrator of the estate of a deceased injured countermeasure recipient. If an injured countermeasure recipient filed a Request Package, but later dies before all benefits are paid by the Program, the executor or administrator of his or her estate may amend the Request Package by filing a new Request Form. The estate will only be entitled to receive benefits under the Program if the original Request Form (previously filed by or on behalf of the injured countermeasure recipient or his or her survivor(s)) was filed within the applicable one-year filing deadline. If such an amendment is filed, all of the documentation submitted with the original Request Package will be considered part of the amended Request Package and the executor or administrator of the estate need not resubmit such documentation. If the injured countermeasure recipient (or his or her survivor(s)) never filed a Request Package, a Request Form filed by the executor or administrator of his or her estate would be considered the beginning of a new Request Package and not an amendment to a previously filed Request Package.

Requesters are responsible for notifying the Program of any changes in circumstances that may have an impact

on the Secretary's eligibility and benefits determinations.

Documentation Required To Be Deemed Eligible (§ 110.50–§ 110.54)

Requesters or their representatives must submit appropriate documentation sufficient to enable the Secretary to determine whether requesters are eligible for Program benefits. The documentation required will vary somewhat depending on whether the requester is filing as an injured countermeasure recipient, survivor, or estate (through the executor or administrator).

Medical Records Necessary To Determine Whether a Covered Injury Was Sustained (§ 110.50)

The phrase "medical records" is defined in § 110.3(p), which provides that "medical records" for purposes of this part means "documentation associated with primary care, hospital in-patient and out-patient care, speciality consultations, and diagnostic testing and results."

Because all Request Packages filed with the Program, including those filed by survivors or executors or administrators of the estates of deceased persons, must relate back to an injured countermeasure recipient who sustained a covered injury, all requesters must submit medical records sufficient to demonstrate to the Secretary that a covered injury was sustained by the injured countermeasure recipient. Section 110.50(a) describes the medical records that are generally required in order for a requester to establish that a covered injury was sustained. The Secretary will use the records submitted, as well as any other available evidence, to evaluate if an injury appearing in a Table (and meeting the requirements of a Table) was sustained or if an injury was otherwise sustained as the direct result of the administration or use of a covered countermeasure. The Program will consider copies of medical records to be the same as the original records. Section 110.50 sets forth all of the medical records necessary for the Secretary to determine whether a covered injury was sustained.

As a general matter, the Secretary expects to receive medical records directly from healthcare providers. The Secretary requires that requesters sign an Authorization for Use or Disclosure of Health Information Form (Authorization for Health Information Form), available from the Program, for each applicable healthcare provider authorizing the release of the requested medical records directly to the Program and send copies of each of these

Authorization for Health Information Forms to the Program. Section 110.50(b) explains that requesters may submit any additional medical documentation that they believe supports their Request Packages. The Program will not expect such documentation. The medical records described in § 110.50(a) generally will be sufficient for the Program to make a covered injury determination. As an example of the type of documentation described in § 110.50(a), a requester may submit scientific evidence such as a scientific research article in order to demonstrate that an injury was directly caused by the administration or use of a covered countermeasure. In making covered injury determinations, the Secretary may consider the scientific evidence available (e.g., published articles concerning a relationship between the countermeasure and an injury) and consult with qualified medical experts.

Section 110.50(c) addresses circumstances in which certain medical records are unavailable to a requester (e.g., a medical office has closed, records have been destroyed due to a natural disaster, a requester is unable to afford the costs charged by a provider to copy and release medical records). In these cases, the requester must provide a statement describing the reasons for the records' unavailability and the reasonable efforts the requester has made to provide them. The Secretary may, at her discretion, accept such a statement from the requester instead of the required medical records, if the circumstances so warrant. In addition, the Secretary may, at her discretion, obtain the records directly from healthcare providers on the requester's behalf.

As described in § 110.50(d), the Secretary may determine that particular records described in § 110.50(a) are not necessary for particular requesters (for example, if certain medical records provide the same information as other records that are submitted) or that additional medical records may be required in order to make a covered injury determination. For example, the Secretary generally requires all medical records for one year prior to the administration or use of a covered countermeasure as necessary to indicate the injured countermeasure recipient's pre-existing medical history. Based on her review of such documents, however, the Secretary may require additional information concerning a condition that was pre-existing prior to the injured countermeasure recipient's administration or use of a covered countermeasure to determine the most likely cause of the covered injury. Also,

depending on the circumstances of the administration or use of the covered countermeasure and the specifications of the relevant PREP Act declaration, the Secretary may need additional information concerning the circumstances of the administration or use of the covered countermeasure to determine whether the specifications of the declaration were satisfied (or that a good faith belief of such existed). The Secretary will notify requesters in such circumstances.

If an injured countermeasure recipient died, and his or her survivors seek a death benefit under the Program, the Secretary will need to review the medical records to determine whether the death was the direct result of a covered injury. As explained in § 110.52(c), the medical records reviewed for this purpose may be the same as those submitted for the covered injury determination.

Documentation an Injured Countermeasure Recipient Must Submit for the Secretary To Make a Determination of Eligibility for Program Benefits (§ 110.51)

Section 110.51 sets forth all of the documentation an injured countermeasure recipient must submit in order for an eligibility determination to be made. First, the requester (or his or her representative) must submit a Request Form. Second, requesters must submit records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure (e.g., medical records, vaccination records, records from an employer or public health authority). Third, a requester must submit the medical records described in § 110.50 sufficient to show that the injured countermeasure recipient sustained a covered injury. Fourth, a requester should submit a copy of each signed Authorization for Health Information Form for each healthcare provider authorizing providers to release medical records directly to the Program. As described in § 110.51(b), the Secretary has the discretion to determine that a requester need not submit a copy of such signed Authorization for Health Information Form with respect to each healthcare provider in all circumstances. Finally, as described in § 110.51(b), a requester may be required to submit additional documentation as required by the Secretary. For example, as a general matter, the information provided on the Request Form, together with other documentation submitted with respect to other requirements, will be sufficient for the Secretary to make a

determination as to whether the injured countermeasure recipient was administered or used a covered countermeasure in accordance with all of the terms of a Secretarial declaration (including administration or use during the effective period of the declaration) or in a good faith belief that the administration or use met all of the terms of a declaration. However, in certain circumstances, the Secretary may require requesters to submit additional documentation in order to make an eligibility determination. In appropriate circumstances, the Secretary may determine that all of the records described in § 110.51 will not be required for a particular injured countermeasure recipient. In such circumstances, the Secretary will notify the requester of such.

Documentation a Survivor Must Submit for the Secretary To Make a Determination of Eligibility for Death Benefits (§ 110.52)

Section 110.52 describes the documentation that a survivor must submit for an eligibility determination to be made with respect to survivor death benefits. With the exception of a Request Form, discussed below, there is no need to duplicate documentation already submitted (by an injured countermeasure recipient during his or her lifetime, by the executor or administrator of his or her estate after death, or by another survivor). With respect to all requests for death benefits (payable only to survivors), at least one survivor must file a Request Form. This is true even if the injured countermeasure recipient already submitted a Request Form and the survivor(s) are amending the previously filed Request Package. Section 110.52 makes clear that all of the documentation required for injured countermeasure recipients must be filed for an eligibility determination to be made with respect to death benefits. Additional documentation is also required (e.g., a death certificate for the injured countermeasure recipient, medical records demonstrating that the death was the direct result of a covered injury, documentation showing that the requester is an eligible survivor). As provided in § 110.52(a)(2), the Secretary has the discretion to accept other documentation that the injured countermeasure recipient is deceased if the death certificate is unavailable and the Secretary is satisfied with a letter submitted by the requester concerning the reasons for the unavailability of the certificate. The Secretary expects that this will be a rare occurrence. In addition, in the place provided on the

Request Form, a survivor filing a Request Form must verify that there are no other eligible survivors or that other eligible survivors exist (together with information about such survivors). As noted above, § 110.11 describes eligible survivors for purposes of death benefits and the priorities of survivorship.

Documentation the Executor or Administrator of the Estate of a Deceased Injured Countermeasure Recipient Must Submit for the Secretary To Make a Determination of Eligibility for Benefits to the Estate (§ 110.53)

The executor or administrator of the estate of a deceased injured countermeasure recipient, seeking benefits under the Program on behalf of the estate, must submit a completed and signed Request Form. This is true even if the injured countermeasure recipient or a survivor already submitted a Request Form and the executor or administrator of the estate is amending the previously filed Request Package. In addition, a death certificate for the injured countermeasure recipient is required. As provided in § 110.53(b), the Secretary has the discretion to accept other documentation showing that the injured countermeasure recipient is deceased if the death certificate is unavailable and the Secretary is satisfied with a letter submitted by the executor or administrator concerning the reasons for the unavailability of the certificate. The Secretary expects that this will be a rare occurrence. Although the estate may receive benefits regardless of whether or not the death resulted from a covered injury, the Secretary may require documentation concerning the death in cases in which eligibility has not yet been determined. For example, the Secretary may require such documentation to help determine whether an injury was caused by the administration or use of a covered countermeasure, as opposed to an underlying health condition that might be apparent at death. No death benefits are awarded to the estate. Finally, documentation showing that the individual is the executor or administrator of the deceased injured countermeasure recipient's estate (e.g., a court order or letters of administration) is required.

Documentation Required for the Secretary To Determine Program Benefits (§ 110.60–§ 110.63)

In addition to the documentation requesters must submit for the Secretary to make eligibility determinations (including the determination that a covered injury was sustained), requesters must submit documentation

to enable the Program to calculate the type and amount of benefits available. Because the benefits available under the Program are secondary to benefits received or receivable from third-party payers, it may be possible that certain requesters who are deemed eligible will not receive benefits from the Program. Sections 110.60–110.63 describe the documentation that is required for requesters seeking particular types of benefits.

Although the Program will accept such documentation at any time after a Request Form is filed, a requester need not submit any of the documentation pertaining to benefits until the Secretary has informed the requester that he or she is eligible under the Program. The submission of benefits documentation is described in § 110.43(b) and is designed to ease the documentary burden on requesters who do not know whether or not they will be deemed eligible.

In order to calculate the amount of each type of benefit available, the Program requires requesters to provide documentation of every third-party payer that may have paid for or provided the benefits requested, or that may have an obligation to do so. The information required concerning such third-party payers with respect to each type of benefit available under the Program is described in §§ 110.60, 110.61, and 110.62. As set forth in § 110.60(a)(3), a requester may need to give consent for the Program to communicate directly with third-party payers.

Requesters seeking medical benefits must also submit documentation concerning the amount paid or expected to be paid by such third-party payers for the medical services or items for which payment is being sought under the Program. Third-party payers of medical benefits include, but are not limited to, medical insurance, Medicaid, Medicare, and any other source of medical reimbursement. An example of the documentation necessary to satisfy this requirement is an Explanation of Benefits form issued by the injured countermeasure recipient's health insurance company.

Third-party payers of benefits for lost employment income include, but are not limited to, the injured countermeasure recipient's employer, disability insurance, workers' compensation programs, and the Department of Veterans Affairs. In order to satisfy his or her obligations under § 110.61, an injured countermeasure recipient may need to submit documentation including his or her earnings and leave statements, information concerning the number of

hours in the requester's standard work day, as well as documentation concerning any programs or payments for lost wages.

Survivors seeking death benefits will have to submit different documentation concerning third-party payers depending on whether they are seeking death benefits under the standard calculation described in § 110.82(b) or are choosing a death benefit under the alternative calculation described in § 110.82(c). For example, survivors seeking a death benefit under the standard calculation must submit documentation concerning PSOB Program death and disability benefits. The legal guardian of survivors seeking a death benefit under the alternative calculation must submit documentation concerning existing or potential third-party payers (described fully in the death benefits calculation section of this preamble and set forth in § 110.82(d)(3)(A)). Survivors seeking death benefits also must submit other documentation described in § 110.62.

Before payments will be made, the representatives of requesters who are minors or adults who lack legal capacity to receive payments must submit additional documentation described in § 110.63. Because some of this documentation may be time-consuming to obtain (e.g., obtaining a court decree establishing a guardianship of the estate for an adult who lacks legal capacity), the requester may wait until a benefits calculation has been made, and a written approval has been issued, before submitting such documentation.

Determinations the Secretary Must Make Before Benefits Can Be Paid (§ 110.70–§ 110.74)

When the Secretary receives a completed and signed Request Form or Request Package postmarked within the filing deadline, she will conduct two separate reviews, as described in § 110.70. First, she will determine whether the requester is eligible for Program benefits. Second, the Secretary will determine the type and amount of any benefits that may be paid.

If the Request Package does not include sufficient documentation to determine eligibility, the Secretary will send written notice to the requester (or his or her representative) identifying the documentation that is needed, as provided for in § 110.71. The requester will be given 60 days to submit the required documentation. If, after reasonable efforts to obtain the documents, the documentation remains unavailable, the requester must submit a letter explaining the circumstances to the Secretary. The Secretary also has the

discretion to accept a letter meeting the requirements set out in § 110.71 as a substitute for the unavailable documentation.

If the Secretary determines that a requester is not eligible for benefits under the Program, she will inform the requester (or his or her representative) of the disapproval in writing. As described in § 110.72(a), the Secretary will provide information as to the options available to the requester, including the requester's right to seek reconsideration of the eligibility decision.

If the Secretary determines that a requester meets the eligibility requirements, she will notify the requester in writing of this decision, at which point the Secretary will review the Request Package in order to calculate the type and amount of the benefits. If the Request Package does not have sufficient documentation for the Secretary to calculate the amount of the benefits, the Secretary will notify the requester in writing of the documentation she requires to complete the calculation. As with the eligibility documentation, the requester will be given 60 days to submit the required documentation or provide a letter setting forth the circumstances that make the records unavailable. Again, the Secretary may accept a letter meeting the requirements set forth in § 110.71 as a substitute for the unavailable documentation. Once the Secretary has sufficient documentation to calculate a requester's benefits, the Secretary will complete this calculation.

As set out in § 110.73, once the Secretary has calculated the amount of the benefits and determined that payment is to be made, she will inform the requester of the approval in writing and then initiate payment. Under § 110.74, if the Secretary disapproves a Request, which the Secretary may do at any time, she will so notify the requester (or his or her representative) in writing and provide information as to the requester's right to seek reconsideration of the Secretary's decision.

Payment of All Benefits Under the Program (§ 110.83)

The Secretary's options in paying all benefits under the Program are described in § 110.83. The Secretary makes all payment decisions, consistent with applicable law, and unilaterally determines the method of payment. If the Secretary determines that there is a reasonable likelihood that payments of medical benefits, benefits for lost employment income, or death benefits paid under the alternative calculation

(described in § 110.82(c)) will be required for a period in excess of a year from the date the Secretary determines that the requester is eligible for such benefits, the Secretary may pay such benefits through a lump-sum payment, a trust such as a U.S. grantor reversionary trust, annuity or medical insurance policy, or appropriate structured settlement agreement (or a combination of these methods), provided they are actuarially determined to have a value equal to the present value of the projected total amount of such benefits that the requester is eligible to receive.

As described in § 110.83(a), lump sum payments will generally be made through electronic funds transfers to requesters' accounts. Under § 110.83(b), if a requester is a minor, the payment will be made on the minor's behalf to the account of the minor's legal guardian (generally, the minor's parent). The legal guardians of minor requesters under this Program will be required to use the payments for the benefit of the minor. Such legal guardians are subject to applicable State law requirements concerning payments made on behalf of minors (e.g., become the guardian of the minor's estate or establish an account with State court supervision, if required by State law). Such legal guardians are also required to provide to the Secretary documentation of guardianship or conservatorship; however, the Secretary may waive this requirement for good cause. Section 110.83(b) describes the requirements pertaining to lump sum payments made on behalf of adults who lack the legal capacity to receive payments.

As provided in § 110.83(c), the Secretary may choose to make interim payments of benefits under the Program (in other words, issue a payment for a certain type or portion of Program benefit prior to making the final benefits payment) to give certain benefits to a requester more quickly than would otherwise be possible. For example, the Secretary may pay medical benefits for past services or items to an eligible requester whose covered injury has resulted in substantial medical bills before making the final determination concerning the payment of future medical benefits. In certain cases, the Secretary may make an interim payment of benefits even before a final eligibility or benefits determination is made. The Secretary expects such instances to be rare, and the requester in such circumstances must agree to repay the Secretary for any benefits later determined to be unavailable under the Program.

The Tax Consequences of Receiving Benefits from the Program

The Secretary is asking the Internal Revenue Service (IRS) to provide prompt guidance on the tax consequences of receiving benefits under the Program. The Program will share this guidance as soon as it is received.

The Secretary's Right To Recover Benefits Paid Under this Program From Third-Party Payers (§ 110.84)

As described above, the payment of benefits under this Program is secondary to benefits available from other third-party payers. The category of third-party payers that have primary responsibility to pay for or provide such benefits is different for each type of benefit available under this Program. Such third-party payers are discussed in the sections of the preamble concerning the different types of benefits. As described in § 110.84, after the Secretary pays benefits under this Program, she will be subrogated to the rights of the requester, meaning that the Secretary may assert a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits. The Secretary may recover from such a third-party payer the amount of benefits the third-party payer has (or had) an obligation to pay for (or provide) or may recover them from the requester if they were paid to the requester. For example, if the Secretary pays a requester \$10,000 in benefits for lost employment income under this Program and a State workers' compensation program later determines that it is obliged to pay the requester \$5,000 in workers' compensation benefits, the Secretary may pursue a claim against the State for \$5,000 (because the Secretary, as the secondary payer, would only be obligated to pay the requester \$5,000 in benefits for lost employment income). No benefits paid under this Program are subject to any lien by any third-party payer.

Reconsideration of the Secretary's Eligibility and Benefits Determinations (§ 110.90)

Every individual who has filed a Request Package and has received a determination by the Secretary either disapproving eligibility for benefits or denying a category or amount of benefits requested has a right to seek reconsideration of the Secretary's determination(s). However, no reconsiderations may be filed concerning the mechanisms of payment.

Although such initial determinations are characterized as Secretarial

determinations, this decision-making authority will be delegated to the Program. The requester or his or her representative must send a letter seeking reconsideration to the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, at the address provided in § 110.90(b). The letter must be received by the Department within 60 calendar days of the date of the Department's determination letter. The letter should state the reasons why the determination should be reconsidered. No new documentation may be included with this letter.

The Associate Administrator, Healthcare Systems Bureau, will convene a panel to review all cases seeking reconsideration. The panel will consist of qualified individuals who are independent of the Program. The panel will review the documentation that was before the Secretary at the time of the determination (and will not consider any new documentation submitted by the requester).

After reviewing the record, the panel will make a recommendation to the Associate Administrator, Healthcare Systems Bureau, who will then make a final determination as to whether or not the requester is eligible for benefits or as to the type and/or amount of benefits that may be paid. The Associate Administrator will inform the requester or his or her representative in writing of the determination(s) and of the reasons. This decision will be considered the Secretary's final action on the issue for which reconsideration was sought. Requesters may not seek review of such a decision.

If the Associate Administrator's final decision is that a requester who was determined to be ineligible for benefits is, in fact, eligible, then the Secretary will make a determination as to the type and amount of benefits to be paid. The requester then has a right to seek reconsideration of the Secretary's determination on that issue.

Secretary's Review Authority and No Additional Judicial or Administrative Review of Determinations Made Under This Regulation (§ 110.91, § 110.92)

In accordance with section 262(f)(1) of the PHS Act (SEPPA) (42 U.S.C. 239a(f)(1)) and as described in § 110.91, the PREP Act authorizes the Secretary to review at any time, on her own motion or on application, any determination made concerning eligibility, and the calculation and amount of benefits under the Program and authorizes the Secretary to affirm, vacate, or modify such determination in any manner the Secretary deems appropriate. The

decision of whether to engage in such a review rests within the complete discretion of the Secretary.

However, as explained in § 110.92, once the Secretary has made a final decision as to eligibility or type or amount of benefits and the requester has exercised his or her right to reconsideration, the PREP Act, referencing section 262(f)(2) of the PHS Act (SEPPA) (42 U.S.C. 239a(f)(2)), does not allow any further review of that decision by any court or administrative body (unless the President specifically directs further administrative review). Given this broad statutory prohibition against further review, no determination made under this part (including, but not limited to, eligibility determinations, benefits calculations, payment decisions, and reconsideration decisions) will be subject to any review by Federal or State courts.

Finally, there is also no judicial review of the Secretary's determinations establishing or amending a Covered Countermeasure Injury Table.

Justification for Omitting Notice of Proposed Rulemaking and for Waiver of Delayed Effective Date

Through the enactment of the PREP Act, the Secretary was authorized to establish and administer the Program. Congress authorized the Secretary to issue regulations implementing the PREP Act as the Secretary deems reasonable and necessary. In accordance with that statutory authority, the Secretary is herein establishing the procedures and requirements to govern the Program.

In addition, the Secretary has determined, under 5 U.S.C. 553(b), that it is contrary to the public interest to follow proposed rulemaking procedures (*i.e.*, issuing a proposed rule, with an accompanying solicitation of public comments) before issuance of these regulations, because such a process might delay the continuing implementation of the President's plan to protect the population of the United States against public health pandemic, epidemic, or security threats. The sooner this regulation is in effect, the sooner the Program can be implemented and potential requesters who may have been seriously injured by a covered countermeasure will be able to be considered for medical and lost employment income benefits. Further, survivors of those who they believe have died as a result of a covered countermeasure will be able to apply for death benefits. Once this implementing regulation is in effect, the Secretary expects individuals who believe that they may be eligible for benefits under

the Program will file requests for such benefits within a short time frame since Letters of Intent to request benefits have already been filed with the Program. In addition, publishing this regulation promptly is necessary to make the remedies afforded by this Program available to potential requesters as soon as possible given the governing one year filing deadline. As noted above, the Secretary has made every effort to enable those who suffer covered injuries as the result of covered countermeasures to have an opportunity to apply for benefits under this Program. As described above, to the extent that scientific evidence linking a covered countermeasure to an injury becomes available and such injury is added to a Table, potential requesters will be able to take advantage of an alternative filing deadline, which may increase the likelihood that their Request Forms will be timely filed. In addition, the Secretary may rely upon constructive receipt of filing, as described in § 110.42(e). The Secretary further believes that her omission of a Notice of Proposed Rulemaking and delay of the effective date of this regulation is warranted given that most of the eligibility and benefits criteria under this Program are the same as those included in the SVICP's administrative implementation regulations—42 CFR part 102. Public comments with respect to those regulations were solicited, received, and considered by the Secretary. For the same reasons, the Secretary has determined that there is good cause to waive a delay in the rule's effective date. Nonetheless, as noted above, comments on the procedures and requirements in this interim final rule will be accepted at the above listed address for a period of 60 days following the rule's publication in the **Federal Register**. Thus, although the rule is effective immediately upon publication, the Secretary will consider the comments received and, based on them, may amend the procedures and/or requirements pertaining to this Program.

Economic and Regulatory Impact

Unfunded Mandates Reform Act of 1995: The Secretary has determined that this interim final rule will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Federalism Impact Statement: The Secretary has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have

“federalism implications.” The rule does not “have substantial direct effects on the states, or on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.”

Impact on Family Well-Being: This interim final rule will not adversely affect the following elements of family well-being: Family safety, family stability, marital commitment; parental rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. In fact, this interim final rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that families of injured persons (and of other persons deemed eligible to receive benefits under this part) receive, or are helped by, medical, lost employment income, and/or death benefits paid under this part without imposing a corresponding burden on them.

Impact of the New Rule: In this interim final rule, the Secretary establishes the procedures and requirements applicable to requesters filing for benefits available under the Program. This interim final rule is based on the PREP Act. It will have the effect of enabling certain eligible individuals who sustained covered injuries as the direct result of receiving a covered

countermeasure under the Secretary’s declaration, to receive benefits under the Program. In the event that an otherwise eligible injured countermeasure recipient has died, his or her estate and/or survivors may be entitled to certain benefits. This interim final rule sets out the eligibility requirements that apply to the Program, how benefits will be calculated, and the documentation that must be submitted.

Paperwork Reduction Act of 1995: Collection of Information: The Countermeasures Injury Compensation Program

Description of Respondents: The respondents will be individuals who sustain serious injuries as a direct result of the administration or use of covered countermeasures (i.e., injured countermeasure recipients) identified by the Secretary in declarations issued under the PREP Act. In addition, respondents may also be certain survivors of individuals who died as the direct result of their covered injuries or their health complications (i.e., eligible survivors of deceased injured countermeasure recipients) and/or the estates of deceased injured countermeasure recipients. Examples of currently covered countermeasures are: the 2009 H1N1 vaccine, the influenza antiviral drugs Tamiflu® and Relenza® when used for pandemic purposes, pandemic influenza diagnostics, personal respiratory devices (e.g., N-95 filtering facepiece respirators to prevent the spread of the 2009 H1N1 virus), and respiratory support devices (e.g., ventilators used for life support for

critically ill patients with respiratory failure due to infection with 2009 H1N1 virus), the influenza intravenous antiviral drug peramivir when used to treat infection with 2009 H1N1, and certain anthrax, smallpox, botulism, and acute radiation syndrome countermeasures.

Estimated Annual Reporting: The estimated annual reporting for this data collection is a total of five hours for reviewing and completing the Countermeasures Injury Compensation Program Request for Benefits Form (Request Form) and the Countermeasures Injury Compensation Program Authorization for Use or Disclosure of Health Information Form (Authorization for Health Information Form) as well as the time to obtain and provide medical and financial documentation for eligibility and the computation of benefits. The respondents listed above will complete the Request Form to inform the CICP of their contact information (e.g., name, address), and the dates and the circumstances under which a covered countermeasure was administered or used. After submitting the Request Form, the eligible respondents listed above will complete the Authorization for Health Information Form to request that medical records be sent to the CICP. The wage rate is the October 2009 average hourly earnings from the Bureau of Labor Statistics, U.S. Department of Labor. The estimated annual response burden is as follows:

| Form | Number of respondents | Responses per respondent | Hourly response | Total burden hours | Wage rate | Total hour cost |
|--|-----------------------|--------------------------|-----------------|--------------------|-----------|-----------------|
| Request for Benefits Form and Supporting Documentation | 2,520 | 1 | 5 | 12,600 | \$18.72 | \$235,872 |
| Authorization for Use or Disclosure of Health Information Form | 2,520 | 1 | 1 | 2,520 | 18.72 | 47,174 |

As a result of the 2009 H1N1 influenza outbreak, this is the first time that covered countermeasures identified in PREP Act declarations are being distributed, administered, and used in the general population of the United States. This is also the first time that the strain of 2009 H1N1 virus has circulated in the United States and worldwide, and the first time that a specific influenza vaccine is available to prevent its illness. In light of these factors, the incidence of potential adverse events associated with this vaccine cannot be predicted. However, as the same technology is utilized in the production of seasonal influenza vaccine, the rate of

vaccine-associated adverse events is not expected to be any different than for seasonal influenza vaccine. Since the behavior of the 2009 H1N1 virus may be unpredictable and the number of people who will get the 2009 H1N1 vaccine is unknown, the CICP estimates of the number of Request for Benefits Forms that will be filed are predicated on currently available information. The CICP expects that individuals with severe injuries are more likely to file requests for benefits since they may have incurred more unreimbursable medical expenses and have more lost employment income than individuals alleging less serious injuries (for whom

the benefits available under the CICP may be limited). Therefore, the estimates of Requests for Benefits assumes that a larger percentage of the more seriously injured will file for Request Packages.

According to the Centers for Disease Control and Prevention (CDC) 127 million doses of 2009 H1N1 vaccine had been distributed to public health agencies and healthcare providers in the United States as of May 28, 2010. Currently, it is estimated that approximately 90 million Americans have been vaccinated, although the precise number is not known. As of May 29, 2010, the Vaccine Adverse Reporting

System (VAERS) has received 11,180 reports related to 2009 H1N1 vaccination. The vast majority (92.2%) of adverse events reported to VAERS after receiving the 2009 H1N1 vaccine have not involved serious health problems or outcomes (*e.g.*, they encompass events such as soreness at the vaccine injection site). Of the 11,180 reports, 868 (7.7 percent) were reports that involved what would be considered serious health events as defined by VAERS. The number of these reports is similar to those historically seen after distribution of a similar number of seasonal flu vaccine doses. Among the 11,180 reports of adverse events, there were 60 reports of deaths. The 60 VAERS reports that involve deaths are under review by CDC, the Food and Drug Administration (FDA) and the States in which the reported deaths occurred. VAERS has received 143 reports of Guillain-Barré Syndrome (GBS), for which follow-up assessments are under way. In the United States, about 80–160 cases of GBS are expected to occur each week, regardless of vaccination. VAERS is a national passive reporting system for vaccine adverse events managed by both CDC and the Food and Drug Administration (FDA) in which reports are submitted voluntarily by people who think an adverse event occurred after vaccination. VAERS accepts reports from all sources. VAERS is useful as a signal detection system to monitor for potential vaccine safety problems.

As outlined above, VAERS has received 868 serious reports and 10,312 nonserious reports. Very little 2009 H1N1 vaccine is currently being administered so it can be assumed these numbers may increase slightly but will not change significantly. The CICIP expects 75 percent (or 651) of these reports to result in Requests for Benefits filed with the CICIP, and about 5 percent (or 516) of the reports of less serious injuries to result in Requests for Benefits with the CICIP, for a total of 1,167 Requests.

In April 2009 there were an estimated 50 million courses of FDA approved antiviral drugs in the Strategic National Stockpile (SNS). Eleven million of these 50 million were distributed to project areas (*i.e.*, all U.S. States, territories and jurisdictions). An additional 23 million courses of antiviral drugs were purchased by project areas and held as part of State stockpiles available for distribution to the local level if needed. Assuming all the antiviral drugs provided by the SNS (approximately 11 million courses) and the State-purchased antiviral drugs (approximately 23 million courses) were

distributed to the local level and dispensed, the CICIP expects that approximately 672 Request for Benefits Forms will be filed concerning serious injuries allegedly resulting from covered antivirals. Based on estimates by CICIP staff, the incidence of very serious injuries from antivirals may be 2 in 10 million (10 cases) for anaphylaxis, 1 in 1 million (50 cases) for Toxic Epidermal Necrolysis/Stevens Johnson Syndrome, and 10 in 1 million (500 cases) for bronchospasms. The incidence of less serious injuries from antivirals is 1 in 1 million (50 cases) for skin reactions and 100 in 1 million (5,000 cases) for vomiting. The CICIP estimates that 75 percent of 560 (or 420) of the individuals alleging serious injuries as a result of antivirals qualifying as covered countermeasures will file requests for benefits with the CICIP. However, the CICIP expects that only 5 percent of 5,050 (or 252) of the individuals alleging less serious injuries will file Request Packages with the CICIP because the benefits available to them may be limited.

Certain ventilators used for life support of critically ill patients with 2009 H1N1 infection are covered countermeasures. Critically ill patients with pneumonia and respiratory failure due to 2009 H1N1 infection require invasive mechanical ventilators to assist them with breathing. Many critically ill 2009 H1N1 patients in the intensive care unit require invasive mechanical ventilation for several weeks. Prolonged ventilator use is associated with serious adverse events such as Ventilator Associated Pneumonia (VAP), which has a high mortality rate. The CDC estimates that between 183,000 and 378,000 H1N1-related hospitalizations occurred from April 2009 to January 16, 2010. The mid-level in this range of 2009 H1N1-related hospitalizations is about 257,000. CDC further estimates the 2009 H1N1-related deaths which occurred between April 2009 and January 16, 2010 to be between 8,330 and 17,160. The mid-level in this range of 2009 H1N1-related deaths is about 11,690. (The CICIP expects that these individuals were hospitalized before their deaths). The CICIP estimates that 5 percent of the mid-level (or 12,850) of the individuals hospitalized ended up in the intensive care unit and 25 percent (or 3,213) of them were placed on ventilators. About 10 percent of the 3,213 (or 321) got VAP, and the CICIP estimates that 5% (or 16) will file Requests for Benefits. Using the mid-level range for H1N1-related deaths, the CICIP estimates that 25 percent (or 2,922) were placed on ventilators and about 10

percent (or 292) of them got VAP. The CICIP estimated that 5 percent (or 15) of the survivors or the estates of those that have died as a result of the 2009 H1N1 virus may submit Requests for Benefits alleging that a death was caused by a ventilator. Whether such requests will result in the receipt of benefits depends on many factors, including whether the administration or use of such ventilators met the requirements of the applicable PREP Act declaration (or that a good faith belief of such existed) and whether it is demonstrated that a covered injury was sustained.

A total of 85 million N–95 filtering facepiece respirators were distributed to project areas, with an initial distribution of 25 million occurring in April 2009, and a second distribution of 60 million occurring in October, 2009. However, it is impossible to estimate how many were actually distributed by individual project areas.

In 2009, the Department of Defense (DoD) provided smallpox vaccinations to 176,068 persons which is about four times the number of civilians (39,566) that received the smallpox vaccine between January 2003 and June 2004 when healthcare and emergency workers were receiving the vaccine to prepare to respond to emergency situations. Approximately 65 of the 39,566 civilians filed requests for benefits with the Smallpox Vaccine Injury Compensation Program (SVICP), which ended in January 2008, for injuries that they sustained after being administered the smallpox vaccine. The CICIP is using the experience with the SVICP to derive its estimates of the number of requests for benefits that may be filed with the CICIP for injuries from the smallpox vaccine. The CICIP estimates that since four times as many military personnel received this vaccine as civilians, about four times as many individuals who filed claims with the SVICP will file claims with the CICIP (because military personnel were generally not eligible to receive benefits under the SVICP, but may be eligible to receive benefits under the CICIP). Therefore, the CICIP estimates that about 260 Requests for Benefits for injuries from the smallpox vaccine will be filed.

In 2009, DoD immunized 224,057 individuals with anthrax vaccinations. Since the anthrax vaccine is as reactogenic as the smallpox vaccine, the SVICP experience is used to derive the estimates of the number of request for benefits that will be filed with the CICIP for injuries from the anthrax vaccine. About six times the number of military personnel (224,057) received the anthrax vaccine as healthcare and emergency workers who received the

smallpox vaccine per year. Therefore, the CICIP estimates that about 6 times as many individuals who filed claims with the SVICP will file claims relating to the anthrax vaccine with the CICIP. The CICIP estimates that about 390 requests for benefits for injuries from the anthrax vaccine will be filed. It is important to note that these estimates do not reflect the Secretary's assessment of the actual number of serious injuries or deaths resulting from the covered countermeasures described here. VAERS is a passive reporting system and has inherent limitations. Although it is a useful resource to generate hypotheses, it cannot be relied on to reach conclusions concerning the numbers of serious injuries or deaths actually resulting from particular vaccines. Moreover, even if the injuries are indeed serious and are determined by the Secretary to have resulted from a covered countermeasure, requesters with the CICIP may still be deemed ineligible for benefits (for example, the person using a covered countermeasure may not have satisfied all of the specifications of the pertinent PREP Act declaration, the Request Form might have been filed outside of the one-year filing deadline).

Comments on this information collection activity should be sent to OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053; Fax: (202) 395-3888.

List of Subjects in 42 CFR Part 110

Benefits, Biologics, Compensation, Immunization, Public Health, Pandemic, Countermeasures, Pandemic Influenza, 2009 H1N1 Vaccine, Influenza Antivirals, Tamiflu®, Relenza®, Peramivir, Pandemic Influenza Diagnostics, Personal Respiratory Devices, N-95 Filtering Facepiece Respirators, Respiratory Support Devices, Ventilators, Anthrax, Smallpox, Botulism, Acute Radiation Syndrome.

Dated: July 2, 2010.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

Approved: July 12, 2010.

Kathleen Sebelius,

Secretary.

■ For the reasons stated in the preamble, the Department amends title 42 of the CFR by adding part 110 to read as follows:

PART 110—COUNTERMEASURES INJURY COMPENSATION PROGRAM

Subpart A—General Provisions

Sec.

- 110.1 Purpose.
- 110.2 Summary of available benefits.
- 110.3 Definitions.

Subpart B—Persons Eligible To Receive Benefits

- 110.10 Eligible requesters.
- 110.11 Survivors.

Subpart C—Covered Injuries

- 110.20 How to establish a covered injury.

Subpart D—Available Benefits

- 110.30 Benefits available to different categories of requesters under this Program.
- 110.31 Medical benefits.
- 110.32 Benefits for lost employment income.
- 110.33 Death benefits.

Subpart E—Procedures for Filing Request Packages

- 110.40 How to obtain forms and instructions.
- 110.41 How to file a Request Package.
- 110.42 Deadlines for filing Request Forms.
- 110.43 Deadlines for submitting documentation.
- 110.44 Legal or personal representatives of requesters.
- 110.45 Multiple survivors.
- 110.46 Amending a request package.

Subpart F—Documentation Required for the Secretary To Determine Eligibility

- 110.50 Medical records necessary for the Secretary to determine whether a covered injury was sustained.
- 110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.
- 110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.
- 110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

Subpart G—Documentation Required for the Secretary To Determine Program Benefits

- 110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.
- 110.61 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of lost employment income benefits.
- 110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits.
- 110.63 Documentation a legal or personal representative must submit when filing

on behalf of a minor or on behalf of an adult who lacks legal capacity to receive payment of benefits.

Subpart H—Secretarial Determinations

- 110.70 Determinations the Secretary must make before benefits can be paid.
- 110.71 Insufficient documentation for eligibility and benefits determinations.
- 110.72 Sufficient documentation for eligibility and benefits determinations.
- 110.73 Approval of benefits.
- 110.74 Disapproval of benefits.

Subpart I—Calculation and Payment of Benefits

- 110.80 Calculation of medical benefits.
- 110.81 Calculation of benefits for lost employment income.
- 110.82 Calculation of death benefits.
- 110.83 Payment of all benefits.
- 110.84 The Secretary's right to recover benefits paid under this Program from third-party payers.

Subpart J—Reconsideration of the Secretary's Determinations

- 110.90 Reconsideration of the Secretary's eligibility and benefits determinations.
- 110.91 Secretary's review authority.
- 110.92 No additional judicial or administrative review of determinations made under this part.

Subpart K—Covered Countermeasures Injury Tables

- 110.100 [Reserved]

Authority: 42 U.S.C. 247d-6e.

Subpart A—General Provisions

§ 110.1 Purpose.

This part implements the Public Readiness and Emergency Preparedness Act (PREP Act), which amended the Public Health Service Act (herein after "PHS Act" or "the Act") by including section 319F-3, and section 319F-4 entitled "Covered Countermeasure Process." Section 319F-4 of the PHS Act directs the Secretary of Health and Human Services, following issuance of a declaration under section 319F-3(b), to establish procedures for the Countermeasures Injury Compensation Program (herein after "CICP" or "the Program") to provide medical and lost employment income benefits to certain individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure consistent with a declaration issued pursuant to section 319F-3(b), or in the good faith belief that administration or use of the covered countermeasure was consistent with a declaration. Also, if the Secretary determines that an individual died as a direct result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

§ 110.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to, or on behalf of, requesters determined to be eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 110.32.

(3) Death benefits to certain survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury, as described in § 110.33.

(b) In general, the benefits paid under the Program, are secondary to any obligation of any third-party payer to provide or pay for such benefits. The benefits available under the CICIP usually will be paid only after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits (*e.g.*, medical insurance for medical services or items, workers' compensation program(s) for lost employment income). However, as provided in § 110.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payer makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

§ 110.3 Definitions.

This section defines certain words and phrases found throughout this part.

(a) *Act* or *PHS Act* means the Public Health Service Act, as amended.

(b) *Alternative calculation* means the calculation used in § 110.82(c) of this part for the death benefit available to dependents younger than 18 years old at the time of payment.

(c) *Approval* means a decision by the Secretary or her designee that the requester is eligible for benefits under the Program.

(d) *Benefits* means payments and/or compensation for reasonable and necessary medical expenses or provision of services described in § 110.31, lost employment income described in § 110.32, and/or payment to certain survivors of death benefits described in § 110.33.

(e)(1) *Child* means any natural, illegitimate, adopted, posthumous child, or stepchild of a deceased injured countermeasure recipient who, at the

time of the countermeasure recipient's death is:

- (i) 18 years of age or younger; or
- (ii) Between 19 and 22 years of age and a full-time student; or
- (iii) Incapable of self-support due to a physical or mental disability.

(2) *Posthumous child* means a child born after the death of the parent.

(3) *Stepchild* means a child of an injured countermeasure recipient's spouse but who is not the child of the injured countermeasure recipient. For a stepchild to be eligible for survivor death benefits under the Program, the stepchild's parent must have been married to the injured countermeasure recipient at the time of that injured countermeasure recipient's death, and the stepchild must have been supported by the injured countermeasure recipient.

(f) *Covered Countermeasure* means the term that is defined in section 319F-3(i)(1) of the PHS Act and described in a declaration issued under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(i)(I),(b)). To be a covered countermeasure for purposes of this part, the countermeasure must have been administered or used pursuant to the terms of a declaration, or in a good faith belief of such; and

(1) Administered or used within a State (as defined in § 110.3(aa)), or otherwise in the territory of the United States; or

(2) Administered to, or used by, otherwise eligible individuals—

(i) At American embassies or military installations abroad (such as military bases, ships, and camps); or

(ii) At North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status Agreement) where American servicemen and servicewomen are stationed.

(g) *Covered injury* means death, or a serious injury as described in § 110.20(b), and determined by the Secretary in accordance with § 110.20 of this part, to be:

(1) An injury meeting the requirements of a Covered Countermeasures Injury Table, which is presumed to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or

(2) An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

(h) *Declaration* means a recommendation issued by the Secretary

under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(b)), for the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, following her determination that a specific disease, condition, or threat represents a public health emergency or a credible risk of a future public health emergency.

(i) *Dependent* means, for purposes of lost employment income benefits, a person whom the Internal Revenue Service would consider to be the injured countermeasure recipient's dependent at the time the covered injury was sustained. For purposes of survivor death benefits, *dependent* means a person whom the Internal Revenue Service would consider to be the deceased injured countermeasure recipient's dependent at the time the covered injury was sustained, and who is younger than the age of 18 at the time of filing the Request Form.

(j) *Disapproval* means a decision by the Secretary that the individual requesting benefits is not eligible to receive benefits under the Program for the specified injury that is the basis of the Request for Benefits.

(k) *Effective period of the declaration* means the time span specified in a declaration, or as amended by the Secretary.

(l) *Federal Employees' Compensation Act (FECA) Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under 5 U.S.C. 8101 *et seq.* as amended, and implemented by the United States Department of Labor in regulations codified at 20 CFR part 10, as amended.

(m) *Healthcare provider* means an individual licensed, certified, or registered by an appropriate authority and who is qualified and authorized to provide health care services, such as diagnosing and treating physical or mental health conditions, prescribing medications, and providing primary and/or specialty care.

(n) *Injured countermeasure recipient* means an individual:

(1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:

(i) Meets the specifications of the pertinent declaration; or

(ii) Is administered or uses a covered countermeasure in a good faith belief that he or she is in a category described by paragraph (1)(i) of this definition; and

(2) Sustained a covered injury as defined in § 110.3(g).

(3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(i) or (1)(ii) of this definition, any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

(o) *Lacks legal capacity* means legally incompetent to receive payment(s) of benefits, as determined under applicable law.

(p) *Medical records* means documentation associated with primary care, hospital in-patient and out-patient care, specialty consultations, and diagnostic testing and results.

(q) *Payer of last resort* means that the Program pays benefits secondary to all other public and private third-party payers who have an obligation to pay for such benefits.

(r) *Program* means the Countermeasures Injury Compensation Program (CICP).

(s) *PREP Act* means the *Public Readiness and Emergency Preparedness Act*, codified as sections 319F-3 and 319F-4 of the PHS Act (42 U.S.C. 247d-6d, 42 U.S.C. 247d-6e).

(t) *Public Safety Officers' Benefits (PSOB) Program* means the Program established under Subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, and implemented by the United States Department of Justice in regulations codified at 28 CFR part 32, as amended.

(u) *Representative* (legal or personal) means someone other than the person for whom Program benefits are sought, and who is authorized to file the Request Package on the requester's behalf pursuant to § 110.44.

(v) *Requester* means an injured countermeasure recipient, or survivor, or the estate of a deceased injured countermeasure recipient (through the executor or administrator of the estate) who files a Request Package for Program benefits, or on whose behalf a Request Package is filed, under this part.

(w) *Request Form or Request for Benefits Form* means the document designated by the Secretary for applying for Program benefits under this part.

(x) *Request Package* means the Request Form, all documentation submitted by, or on behalf of, the requester, and all documentation obtained by the Secretary as authorized by, or on behalf of, the requester for determinations of Program eligibility and benefits under this part.

(y) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority conferred on the Secretary under the PREP Act has been delegated.

(z) *Serious injury* means serious physical injury. Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(aa) *Standard calculation* means the calculation used in § 110.82(b) of this part for the death benefit available to all eligible survivors (other than surviving dependents younger than the age of 18 who do not fit the definition of "child" under § 110.3(e)).

(bb) *State* means any State of the United States of America, the District of Columbia, United States territories, commonwealths, and possessions, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia.

(cc) *Survivor* means a person meeting the requirements of § 110.11 with respect to a deceased injured countermeasure recipient who died as a direct result of a covered injury.

(dd) *Table or Table of Injuries* means a Table of Covered Countermeasure Injuries to be included under Subpart K of this part, including the definitions and requirements set out therein.

(ee) *Third-party payer* means the United States (other than for payments of benefits under this Program) or any other third party, including but not limited to, any State or local governmental entity, private insurance carrier, or employer, any public or private entity with a legal or contractual obligation to pay for or provide benefits. The Program is the payer of last resort.

Subpart B—Persons Eligible To Receive Benefits

§ 110.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Injured countermeasure recipients, as described in § 110.3(n);

(2) Survivors, as described in § 110.3(cc) and § 110.11; or

(3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (*i.e.*, executors or administrators).

(b) If a countermeasure recipient dies, his or her survivor(s) and/or the executor or administrator of his or her estate may file a new Request Package (or Request Package(s)) or amend a previously filed Request Package. A new Request Package may be filed whether or not a Request Package was previously submitted by, or on behalf of, the deceased injured countermeasure recipient, but must be filed within the filing deadlines described in § 110.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in § 110.46.

(c) The benefits available to different categories of requesters are described in § 110.30.

§ 110.11 Survivors.

(a) *Survivors of injured countermeasure recipients who died as the direct result of a covered injury.* If the Secretary determines that an injured countermeasure recipient died as the direct result of a covered injury (or injuries), his or her survivor(s) may be eligible for death benefits.

(b) *Survivors who may be eligible to receive benefits and the order of priority for benefits.* (1) The Act uses the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program, except as provided in paragraphs (b)(3), (4), and (5) of this section.

(2) The PSOB Program's categories of survivors (known in the PSOB Program as beneficiaries) and order of priority for receipt of death benefits are detailed under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, as implemented in 28 CFR part 32.

(3) In the PSOB Program, the person who is survived must have satisfied the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased injured countermeasure recipient who would otherwise have been eligible under this part.

(4) Unlike the PSOB Program, if there are no survivors eligible to receive death benefits under the PSOB Program (as set forth in paragraph (b)(2) of this section), the legal guardian of a deceased minor who was a countermeasure recipient may be eligible as a survivor under this Program. Such legal guardianship must

be determined by a court of competent jurisdiction under applicable State law.

(5) A surviving dependent younger than the age of 18 whose legal guardian opts to receive a death benefit under the alternative calculation on the dependent's behalf will have the same priority as surviving eligible children under the PSOB Program (consistent with paragraph (b)(2) of this section) even if the dependent is not the surviving eligible child of the deceased countermeasure recipient for purposes of the PSOB Program. However, such a dependent may only be eligible to receive benefits under the alternative death benefits calculation, described in § 110.82(c), and is not eligible to receive death benefits under the standard calculation described in § 110.82(b). Death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such dependents.

(6) Any change in the order of priority of survivors or of the eligible category of survivors under the PSOB Program shall apply to requesters seeking death benefits under this Program on the effective date of the change, even prior to any corresponding amendment to this part. Such changes will apply to Request Packages pending with the Program on the effective date of the change, as well as to Requests filed after that date.

Subpart C—Covered Injuries

§ 110.20 How to establish a covered injury.

(a) *General.* Only serious injuries, as described in § 110.3(z), or deaths are covered under the Program. In order to be eligible for benefits under the Program, a requester must submit documentation showing that a covered injury, as described in § 110.3(g), was sustained as the direct result of the administration or use of a covered countermeasure pursuant to the terms of a declaration under section 319F-3(b) of the PHS Act (including administration or use during the effective period of the declaration) or as the direct result of the administration or use of a covered countermeasure in a good faith belief that it was administered or used pursuant to the terms of a declaration (including administration or use during the effective period of the declaration). A requester can establish that a covered injury was sustained by demonstrating to the Secretary that a Table injury occurred, as described in paragraph (c) of this section. In the alternative, a requester can establish that an injury was actually caused by a covered countermeasure, as described in paragraph (d) of this section. The

Secretary may obtain the opinions of qualified medical experts in making determinations concerning covered injuries.

(b) *Table injuries.* A Table lists and explains injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by a covered countermeasure, and the time periods in which the onset (*i.e.*, first sign or symptom) of these injuries must occur after administration or use of the covered countermeasures. If an injury occurred within the listed time periods, and at the level of severity required, there is a rebuttable presumption that the covered countermeasure was the cause of the injury. A Table is accompanied by Qualifications and Aids to Interpretation which provide an explanation of the injuries listed on a Table. A requester may establish that a covered injury occurred by demonstrating that the countermeasure recipient sustained an injury listed on a Table, within the time interval defined by the Table's Definitions and Requirements. In such circumstances, the requester need not demonstrate the cause of the injury because the Secretary will presume, only for purposes of making determinations under this Subpart, that the injury was the direct result of the administration or use of a covered countermeasure. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based on her review of the evidence, that a source other than the countermeasure more likely caused the injury. In such circumstances, the Table presumption of causation will be rebutted.

(c) *Injuries for which causation must be shown (non-Table injuries).* If an injury is not included on a Table or if the injury does not meet the requirements set out for an injury that is listed on a Table (*e.g.*, the first sign or symptom of the injury did not occur within the time interval specified on the Table), the requester must demonstrate that the injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury.

(d) *Injuries resulting from the underlying condition for which the countermeasure was administered or used.* An injury sustained as the direct result of the covered condition or

disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

Subpart D—Available Benefits

§ 110.30 Benefits available to different categories of requesters under this Program.

(a) *Benefits available to injured countermeasure recipients.* A requester who is an injured countermeasure recipient may be eligible to receive either medical benefits or benefits for lost employment income, or both.

(b) *Benefits available to survivors.* A requester who is an eligible survivor of a deceased injured countermeasure recipient may be eligible to receive a death benefit if the death was caused by the covered injury or its health complications.

(c) *Benefits available to estates of deceased injured countermeasure recipients.* The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased countermeasure recipient's lifetime, or at the time of death, as a result of a covered injury or its health complications, but have not yet been paid in full by the Program. Such medical benefits and benefits for lost employment income may be available regardless of the cause of death. The estate of the deceased injured countermeasure recipient may not receive a death benefit. Death benefits are only available to certain survivors.

§ 110.31 Medical benefits.

(a) Injured countermeasure recipients may receive payments or reimbursements for medical services and items that the Secretary determines to be reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent the health complications of a covered injury. The Secretary may pay for such medical services and items in an effort to cure, counteract, or minimize the effects of any covered injury, or any health complication of a covered injury, or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of benefits to a requester (*e.g.*, a surgical procedure that lessens the amount of time and expense for the treatment of a covered injury). The

Secretary may make such payments or reimbursements if reasonable and necessary medical services and items have already been provided or if they are likely to be needed in the future. In making determinations about which medical services and items are reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a healthcare provider, and may consider whether the applicable service or item is within the standard of care for that condition.

(b) To receive medical benefits for the health complications of a covered injury, a requester must demonstrate that the complications are the direct result of the covered injury. Examples of health complications include, but are not limited to, ill-effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat a covered injury.

(c) The calculation of medical benefits available under this Program is described in § 110.80. Although there are no caps on medical benefits, the Secretary may limit payments to the amounts that she determines are reasonable for services and items considered reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payer to pay for or provide such services or items to the requester. As provided in § 110.84, the Secretary retains the right to recover medical benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits. Requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. The Secretary reserves the right to disapprove medical benefits if the requester fails to do so.

(d) The Secretary may make payments of medical benefits or reimbursements of medical expenses described in this section to the estate of a deceased injured countermeasure recipient as long as such payments or expenses were accrued during the deceased injured countermeasure recipient's lifetime, or at the time of death, as the result of the covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died.

§ 110.32 Benefits for lost employment income.

(a) Requesters who are determined to be eligible for Program benefits as injured countermeasure recipients may

be able to receive benefits for loss of employment income incurred as a result of a covered injury (or its health complications, as described in § 110.31(b)). Compensation for lost wages is paid as a percentage of the amount of employment income earned at the time of injury and lost as the result of the covered injury or its health complications. The period of time requested for lost employment income benefits must be supported by the severity of the covered injury as demonstrated by the medical and employment records.

(b) The method and amount of benefits for lost employment income are described in § 110.81. Benefits for lost employment income will be adjusted if there are fewer than ten days of lost employment income. Pursuant to law, and as described in § 110.81, benefits provided for lost employment income may also be adjusted for annual and lifetime caps. Payment of benefits for lost employment income is secondary to any obligation of any third-party payer to pay for lost employment income or to provide disability or retirement benefits to the requester. It is the obligation of requesters to follow all specified procedures to apply for and acquire third-party benefits. The Secretary has the discretion to disapprove lost employment income benefits if the requester fails to do so. As provided in § 110.84, the Secretary reserves the right to recover lost employment income benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits.

(c) The Secretary does not require an individual to use paid leave (*e.g.*, sick leave or vacation leave) for lost work days. However, if an individual uses paid leave for lost work days, the Secretary will not consider those days to be days of lost employment income unless the individual reimburses the employer for the paid leave taken and the employer restores the leave that was used. This puts the individual back in the same position as if he or she had not used paid leave for the lost work days.

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased injured countermeasure recipient as long as such benefits were accrued during the deceased injured countermeasure recipient's lifetime as the result of a covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure

recipient, of death benefits under § 110.82.

§ 110.33 Death benefits.

(a) Eligible survivors may be able to receive a death benefit under this Program if the Secretary determines that an otherwise eligible countermeasure recipient sustained a covered injury and died as a direct result of the injury or its health complications. The method and amount of death benefits are described in § 110.82. As provided in § 110.84, the Secretary retains the right to recover death benefits paid by the Program if third-party payers are obligated to provide those benefits. There are two different calculations for death benefits: the standard calculation and the alternative calculation.

(b) The standard calculation, described in § 110.82(b), is based upon the death benefit available under the PSOB Program and is available to all eligible survivors with one exception (surviving dependents younger than the age of 18 who do not fit the definition of "child" under § 110.3(e)). In the event that death benefits were paid under the PSOB Program with respect to the deceased injured countermeasure recipient, no death benefits may be paid under the standard calculation. In addition, death benefits under this standard calculation are secondary to disability benefits under the PSOB Program. If a disability benefit was paid under the PSOB Program, the amount of that disability benefit would be deducted from benefits payable under the standard calculation.

(c) The alternative calculation, described in § 110.82(c), is based on the injured countermeasure recipient's employment income at the time of the covered injury. Payment under this calculation is only available to surviving dependents who are younger than the age of 18 at the time of payment. The legal guardian(s) of such surviving dependents must select the death benefit as calculated under this alternative calculation before it will be paid. Annual and lifetime caps may apply. The payment of a death benefit as calculated under this alternative calculation is secondary to other benefits paid or payable with respect to the deceased injured countermeasure recipient, namely:

(1) Compensation for loss of employment income (except for lost employment income under this Program);

(2) Death or disability benefits (*i.e.*, payments including, but not limited to, those under the PSOB Program) on behalf of the dependent(s) or their legal guardian(s);

(3) Retirement benefits on behalf of the dependent(s) or their legal guardians; or

(4) Life insurance benefits on behalf of the dependent(s).

Subpart E—Procedures for Filing Request Packages

§ 110.40 How to obtain forms and instructions.

(a) Copies of all necessary forms and instructions will be available:

(1) By writing to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857.

(2) By calling 1-888-ASK-HRSA. This is a toll-free number.

(3) By downloading them from the Internet at <http://www.hrsa.gov/countermeasurescomp/>. Click on the link to "Forms and Instructions."

(b) Before reviewing a Request for Benefits, the Secretary will assign a case number to the Request for Benefits and so inform the requester (or his or her representative) in writing. All correspondence to the requester (or his or her representative) about a specific Request for Benefits will be referenced by this case number.

§ 110.41 How to file a Request Package.

A Request Package comprises all the forms and documentation that are submitted to enable the Secretary to determine eligibility and calculate benefits. Request Packages may be submitted through the U.S. Postal Service, commercial carrier, or private courier service. The Countermeasures Injury Compensation Program will not accept Request Packages that are hand-delivered. Electronic submissions are not currently accepted, but may be in the future. The Program will publish a notice if electronic filing becomes available. Requesters (or their representatives) should send all forms and documentation to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857. All documentation to the Program must include the case number once one has been assigned to the requester.

§ 110.42 Deadlines for filing Request Forms.

(a) *General.* All Request Forms (or Letters of Intent, described in paragraph (b) of this section) must be filed within one year of the date of the administration or use of a covered

countermeasure that is alleged to have caused the injury. If no previous Request Form (or Letter of Intent) has been filed, this deadline also applies to survivor(s) of an injured countermeasure recipient who is deceased, and to the executor or administrator of his or her estate. If a Request Form (or Letter of Intent) was previously filed, § 110.46 describes amendments to Request Packages.

(b) *Letters of Intent.* Until Request Forms and Instructions are available, requesters must file a Letter of Intent to File, in order to establish that their Requests for Benefits are timely filed within the one-year deadline. Directions for submitting a Letter of Intent (to file) are available on the Program's Web site at <http://www.hrsa.gov/countermeasurescomp/> or by calling 1-888-ASK-HRSA. Even once Request Forms are available, the Secretary has the discretion to accept Letters of Intent (to file) for purposes of meeting the filing deadline. However, when Request Forms and Instructions are available, all requesters who have submitted Letters of Intent must still file Request Forms as soon as possible.

(c) *Determination of proper filing.* The filing date is the date the Request Form (or Letter of Intent) is postmarked. A legibly dated receipt from a commercial carrier, a private courier service, or the U.S. Postal Service will be considered equivalent to a postmark. If and when Request Forms are accepted electronically, the filing date is the date the Request Form is submitted electronically. A Request Form will not be considered filed unless it has been completed (to the fullest extent possible) and signed by the requester or his or her personal or legal representative. After filing a Request Form within the governing filing deadline, a requester must update the Request Package to reflect new information as it becomes available (e.g., copies of medical records generated after the initial submission of the Request Package).

(d) *Request Forms not filed within the one-year deadline.* If the Secretary determines that a Request Form or Letter of Intent was not filed within the governing filing deadline set out in this section, the Request Form (or Letter of Intent) will not be processed and the requester will not be eligible for benefits under this Program.

(e) *Constructive receipt.* The Secretary reserves the right to consider a legal claim filed with the Federal Government (e.g., a Federal Tort Claims Act claim or a petition with the National Vaccine Injury Compensation Program) concerning an alleged injury resulting

from the administration or use of a covered countermeasure to be a filing of a Request Form or Letter of Intent for purposes of determining the filing date under this Program. The date of such constructive filing will be the official filing date of the action, *i.e.*, when all applicable requirements for proper filing in that forum have been met.

(f) *Request Forms (or amendments to Request Forms) based on initial publication of a Table of Injuries or modifications to an existing Table.* The Secretary may publish a new Table (or Tables) by amendment(s) to subpart K of this part. The effect of such a new Table or amendment may enable a requester who previously could not establish a Table injury to do so. In such circumstances, the requester must file a new Request Form if one was previously submitted and eligibility was denied or if one was not previously submitted within one year after the effective date of the establishment of, or amendment to, the Table. If the Secretary has not made a determination, she will automatically review any pending Request Forms in light of the new or amended Table(s).

§ 110.43 Deadlines for submitting documentation.

(a) *Documentation for eligibility determinations.* A requester will satisfy the filing deadline as long as the signed Request Form is completed (to the fullest extent possible) and submitted within the governing filing deadline described in § 110.42. The Secretary generally will not begin review of a requester's eligibility until all the documentation necessary to make this determination has been submitted.

(b) *Documentation for benefits determinations.* Although the Secretary will accept documentation required to make benefits determinations (*i.e.*, calculate benefits available, if any) at the time the Request Form is filed or any time thereafter, requesters need not submit such documentation until they have been notified that the Secretary has determined eligibility. The Secretary will not generally begin review of the benefits available to a requester until the documentation necessary to make a benefits determination has been submitted.

§ 110.44 Legal or personal representatives of requesters.

(a) *Generally.* Persons other than a requester (e.g., a lawyer, guardian, family member, friend) may file a Request Package on a requester's behalf as his or her legal or personal representative. A requester need not use the services of a lawyer to apply for

benefits under this Program. A legal representative, or a personal representative (who does not need to be a lawyer) is only required, as described in this section, for requesters who are minors or adults who lack legal capacity to receive payment of benefits. In the event that a legal or personal representative files on behalf of a requester, the representative will be bound by the obligations and documentation requirements that apply to the requester (*e.g.*, if a requester is required to submit employment records, the representative must file the requester's employment records). The representative must also satisfy the requirements specific to representatives set out in this part. If a requester has a representative, the Program will generally direct all communications to the representative. However, the Secretary reserves the right of the Program to contact the requester directly if necessary, and to conduct a follow-up survey to determine the ability of the Program to meet requesters' needs.

(b) *Legal or personal representatives of legally competent adults.* A requester who is a legally competent adult may use a legal or personal representative to submit a Request Package on his or her behalf. In such circumstances, the requester must indicate on the Request Form that he or she is authorizing the representative to seek benefits under this Program on his or her behalf.

(c) *Legal or personal representatives of minors and adults who lack legal capacity to receive payment of benefits.* A requester who is a minor or an adult who lacks legal capacity to receive payment of benefits must use a legal or personal representative to apply for benefits under this Program on his or her behalf. In such circumstances, the representative must indicate, in the place provided on the Request Form, that the requester is a minor or an adult who lacks legal capacity to receive payment of benefits and that the representative is filing on behalf of the requester. In addition, before the requester will be paid by the Program, the representative must submit the documentation described in § 110.63. A minor who is emancipated, as determined by a court of competent jurisdiction, does not need a legal or personal representative to file a Request Form or Request Package on his or her behalf.

(d) *No payment or reimbursement for legal or personal representatives' fees or costs.* The Act does not authorize the Secretary to pay for, or reimburse, any fees or costs associated with the requester's use of the services of a legal

or personal representative under this Program, including those of an attorney.

§ 110.45 Multiple survivors.

Multiple survivors of the same deceased injured countermeasure recipient may file Request Forms separately or together. Multiple survivors may also submit one set of any required documentation on behalf of all of the requesting survivors as long as such documentation is identical for each survivor.

§ 110.46 Amending a Request Package.

(a) *Generally.* All requesters may amend their documentation concerning eligibility up to the time the Secretary has made an eligibility determination. Requesters are expected to submit additional medical records as they become available. Requesters also may amend their information or documentation concerning the calculation of benefits until the Secretary has made a benefits determination. Once an *eligibility* determination has been made, the Secretary will not accept additional documentation concerning eligibility, except as described in paragraphs (b) and (c) of this section. Once a *benefits* determination has been made, the Secretary will not accept additional documentation regarding the type or amount of benefits for that covered injury, except as described in paragraphs (b) and (c) of this section.

(b) *Requesters who are survivors.* If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies, or the executor or administrator timely filed on behalf of the estate, the survivor(s) may amend the previously filed Request Package at any time by filing a new Request Form in order to be considered for death benefits. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased injured countermeasure recipient's Request Package. However, a survivor filing an amendment to a previously filed Request Package may only be eligible for benefits if the previously filed Request Package was filed within the governing filing deadline. All documentation that has already been submitted with respect to the deceased injured countermeasure recipient will be considered part of the survivor requester's Request Package, and he or she is not required to resubmit such documentation. Survivor requesters must also file an amendment to a Request Package if there is a change in the order of priority of survivors, as described in § 110.11.

(c) *Requests in which the benefits are sought for the estate of a deceased injured countermeasure recipient.* If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies before all due benefits are paid by the Program, the executor or administrator of his or her estate may amend his or her Request Package at any time in order for the estate to be considered for benefits. This opportunity to amend applies also if the Request Form was timely filed by a survivor. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased injured countermeasure recipient's Request Package. However, the executor or administrator of the deceased injured countermeasure recipient's estate filing an amendment to a previously filed Request Package may only be eligible to receive benefits on behalf of the estate if the previously filed Request Package was filed within the governing deadline. All documentation that has already been submitted with respect to the deceased injured countermeasure recipient will be considered part of that person's Request Package, and the executor or administrator of the estate is not required to resubmit such documentation.

Subpart F—Documentation Required for the Secretary To Determine Eligibility

§ 110.50 Medical records necessary for the Secretary to determine whether a covered injury was sustained.

(a) In order to determine whether an injured countermeasure recipient sustained a covered injury, a requester must arrange for his or her medical providers to submit to the Program the following medical records, as defined in § 110.3(p):

(1) All medical records documenting medical visits, procedures, consultations, and test results that occurred on or after the date of administration or use of the covered countermeasure; and

(2) All hospital records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all physician and nursing progress notes, and all test results that occurred on or after the date of administration or use of the covered countermeasure; and

(3) All medical records for one year prior to administration or use of the covered countermeasure as necessary to

indicate an injured countermeasure recipient's pre-existing medical history.

(b) A requester may submit additional medical documentation that he or she believes will support the Request Package. Although generally not required if a Table injury was sustained, a requester may introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure. Letters from treating physicians may be submitted as additional evidence, but may not substitute for the medical documentation required in paragraph (a) of this section.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the Program after the requester has made reasonable efforts to facilitate the records being sent to the Program, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has made to arrange for the health care providers to submit them. The Secretary has the discretion to accept this statement in place of the unavailable medical records. In this circumstance, the Secretary may attempt to obtain the records on the requester's behalf.

(d) In certain circumstances, the Secretary may require additional records to make a determination that a covered injury was sustained (e.g., medical records more than one year prior to the date of administration or use of the covered countermeasure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination.

(e) Although the Secretary prefers to receive medical records directly from healthcare providers, she has the discretion to accept them from the requester.

§ 110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.

(a) An injured countermeasure recipient (or his or her legal or personal representative) must submit all of the following documentation in order for the Secretary to make a determination of eligibility:

(1) A completed and signed Request Form submitted within the filing deadline described in § 110.42; and

(2) Records sufficient to demonstrate that the injured countermeasure recipient used or was administered a covered countermeasure; and

(3) Records sufficient to demonstrate that the injured countermeasure

recipient sustained a covered injury, as defined in § 110.3(g), in accordance with the requirements set forth in § 110.50; and

(4) A copy of each signed Authorization for Health Information Form authorizing the release of records to the Program that was sent by the requester to each healthcare provider instructing that the records be submitted directly to the Program.

(b) In certain circumstances, some of the above documentation may not be required, or additional documentation may be required, in which case the Secretary will so notify the requester. For example, the Secretary may require records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure in accordance with the provisions of a Secretarial declaration, or in the good faith belief that it was so administered or used, if she is unable to determine this from the records submitted. In order to meet the specifications of a declaration, some individuals will need to show that the activity giving rise to the injury (i.e., administration or use of the covered countermeasure) was authorized in accordance with the public health and medical response of the Authority Having Jurisdiction, as defined in the pertinent declaration, to prescribe, administer, deliver, distribute or dispense the covered countermeasure following a declaration of an emergency, as defined in the pertinent declaration. For purposes of this part, this requirement can be satisfied by showing that the covered countermeasure was administered or used following the declaration of an emergency, as defined in the pertinent declaration, by an Authority Having Jurisdiction, as defined in the pertinent declaration either:

(1) Pursuant to a written agreement or other formal arrangement with an Authority Having Jurisdiction; or

(2) In accordance with the written recommendations of an Authority Having Jurisdiction.

§ 110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.

(a) A requester who is a survivor under § 110.11 must submit the following documentation in order for a determination of eligibility for a death benefit to be made:

(1) All of the documentation required for individuals in § 110.51. There is no need to duplicate documentation already submitted to satisfy the requirements of other subparts in this

part. For example, if the deceased injured countermeasure recipient had previously filed, the documentation submitted does not have to be re-submitted; and

(2) A death certificate for the deceased countermeasure recipient. If a death certificate is unavailable, the requester must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Medical records sufficient to establish that the deceased injured countermeasure recipient died as the result of the covered injury or its health complications. Such medical records may be the same as those required under § 110.50. If an autopsy was performed, the requester must submit a complete copy of the final autopsy report; and

(4) Documentation showing that the requester is an eligible survivor, pursuant to § 110.11 (e.g., birth certificate or marriage certificate); and

(5) Verification, on the place provided on the Request Form, either that there are no other eligible survivors (e.g., for surviving eligible children, that there is no surviving spouse, no other surviving eligible children, and no other surviving dependents younger than the age of 18 who may be eligible for the death benefit under the alternative calculation) or that other eligible survivors exist (along with the information known about such survivors). Section 110.11 describes eligible survivors and the priorities of survivorship; and

(6) Even if a Request Form had previously been filed by the injured countermeasure recipient, the survivor(s) must submit a new Request Form.

(b) [Reserved]

§ 110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

(a) The executor or administrator of the estate of a deceased injured countermeasure recipient must submit the following documentation in order for a determination of eligibility for benefits to the estate to be made:

(1) All of the documentation required for individuals in § 110.51;

(2) A death certificate for the deceased injured countermeasure recipient. If a death certificate is unavailable, the executor or administrator must submit a letter providing the reasons for its

unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Documentation showing that the individual is the executor or administrator of the estate of the deceased injured countermeasure recipient, *e.g.*, Letter of Administration issued by a court of competent jurisdiction; and

(4) Even if a Request Form had previously been filed by the injured countermeasure recipient, the executor or administrator of the estate must submit a new Request Form.

(b) [Reserved]

Subpart G—Documentation Required for the Secretary To Determine Program Benefits

§ 110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks payment or reimbursement for medical services or items must provide the following, in addition to the documentation submitted under subpart F of this part:

(1) *List of third-party payers.* The requester must submit a list of all third-party payers that may have an obligation to pay for or provide any medical services or items to the injured countermeasure recipient for which payment or reimbursement is being sought under this Program. Such third-party payers may include, but are not limited to, health maintenance organizations, health insurance companies, workers' compensation programs, Medicare, Medicaid, Department of Veterans Affairs, military treatment facilities (MTFs), and any other entities obligated to provide medical services or items or reimburse individuals for medical expenses. Such a list must include the injured countermeasure recipient's account numbers and other applicable information. If the requester knows of no such third-party payer, he or she must so certify in writing. If the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

(2) *Documents for medical services or items provided since the onset of the covered injury.* A requester seeking payment or reimbursement for medical

services or items already provided for a covered injury or its health complications must submit an itemized statement from each healthcare provider or entity (*e.g.*, clinic, hospital, doctor, or pharmacy) and third-party payer listing the services or items provided to diagnose or treat the covered injury or its health complications and the amounts paid or expected to be paid by third parties for such services or items (*e.g.*, an Explanation of Benefits from the individual's health insurance company). If no third-party payer has an obligation to pay for or provide such services or items, the requester must so certify in writing and submit an itemized list of the services or items provided (including the total cost of such services or items). To assist the Secretary in making a determination as to whether such services or items were reasonable and necessary to diagnose or treat a covered injury, or to diagnose, treat, or prevent its health complications, the requester may submit, in addition to the required medical records, documentation showing that a health-care provider prescribed or recommended such services or items. The medical records must support the requested services and items.

(3) *Documents for medical services and items expected to be provided in the future.* A requester seeking payments for medical services or items resulting from a covered injury or its health complications expected to be provided in the future must submit a statement from each healthcare provider (*e.g.*, a treating neurologist for neurological issues and a treating cardiologist for cardiac issues) describing those services and items that appear likely to be needed to diagnose or treat the covered injury, or to diagnose, treat, or prevent its health complications, in the future. The medical records must support the requested services and items. A requester must submit documentation, if available, concerning the likely cost of, and the amount expected to be covered by third-party payers for, such services or items. Consent for the Program to communicate directly with the healthcare providers may also be required.

(b) [Reserved]

§ 110.61 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of lost employment income benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks benefits for lost employment income must provide, in

addition to the documentation submitted under subpart F of this part, documentation describing:

(1) The number of days (including partial days) of work missed by the injured countermeasure recipient as a result of the covered injury or its health complications for which employment income was lost (*e.g.*, time sheet from the relevant pay period(s) showing work days missed). As stated in § 110.32(c), days for which an individual used paid leave will be considered days of work for which employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days; and

(2) The injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return or pay stub(s) from all employers at the time of the covered injury); and

(3) Whether the injured countermeasure recipient had one or more dependents at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return at the time of the covered injury); and

(4) A list of all third-party payers that have paid, or that may be obligated to pay, benefits to the injured countermeasure recipient for loss of employment income or provide disability and/or retirement benefits for which payment or reimbursement is being sought under this Program (*e.g.*, State workers' compensation programs, disability insurance programs, Uniform Services Retirement Board determinations, Department of Veterans Affairs determinations, etc.). A requester must submit documentation, if available, concerning the amount of such payments or benefits paid or payable to, or on behalf of, the injured countermeasure recipient by third-party payers. If the requester knows of no such third-party payer, he or she must so certify in writing. If, at any time, the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

(b) [Reserved]

§ 110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits.

(a) A requester determined by the Secretary to be an eligible survivor and who seeks a death benefit under § 110.82(b) (the standard calculation) must provide, in addition to the documentation submitted under subpart F of this part, a written certification informing the Secretary whether a disability or death benefit was paid or payable under the PSOB Program with respect to the deceased injured countermeasure recipient. If such benefit was provided, the requester must submit documentation showing the amount of the benefit paid by the PSOB Program. If the deceased injured countermeasure recipient was covered under the PSOB and no such benefit was, or will be provided, the certification must explain whether any survivors are eligible for a death benefit under the PSOB Program and, if so, whether a death benefit may be paid or payable under the PSOB Program.

(b) The legal guardian seeking a death benefit under § 110.82(c) (the alternative calculation) on behalf of a dependent younger than the age of 18 determined by the Secretary to be an eligible survivor must provide, in addition to the documentation submitted under Subpart F of this part, the following:

(1) Documentation showing that the deceased injured countermeasure recipient is survived by one or more dependents younger than the age of 18. Such documentation must show the date of birth of all such dependents (*e.g.*, copies of birth certificates);

(2) Documentation showing that the requester is the legal guardian of all of the dependents described in paragraph (b)(1) of this section, as required under § 110.63(a). If multiple dependents have different legal guardians, the legal guardian of each of the dependents must submit such documentation;

(3) A written selection by each legal guardian, on behalf of all of the dependents described in paragraph (b)(1) of this section for whom he or she is the legal guardian, to receive proportional death benefits under the alternative calculation as described in § 110.82(c), in place of proportional benefits available under the standard calculation as described in § 110.82(b). Written selections are described in § 110.82(c)(1);

(4) Documentation showing the deceased injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the decedent's Federal tax return or pay stub(s) from all

employers at the time of the covered injury); and

(5) A description of all third-party payers that have paid for, or that may be required to pay for, the benefits described in § 110.82(c)(3)(i). This description must include the amount of such benefits that have been paid or that may be paid in the future. If the representative knows of no such third-party payer, he or she must so certify in writing. If, at any time, the representative becomes aware that a third-party payer may have such an obligation, he or she must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

§ 110.63 Documentation a legal or personal representative must submit when filing on behalf of a minor or on behalf of an adult who lacks legal capacity to receive payment of benefits.

Before benefits will be paid by the Program to an eligible requester who is a minor or an adult who lacks legal capacity to receive payment of benefits, his or her legal or personal representative must submit the following, in addition to the documentation required under Subpart F of this part and, as applicable, §§ 110.60–110.62:

(a) For an eligible requester who is a minor:

(1) Documentation showing that the requester is a minor (*e.g.*, birth certificate); and

(2) Documentation showing that the representative is the legal guardian of the property or estate of the minor (*e.g.*, appointment of guardianship by a court of competent jurisdiction). If a minor has more than one legal guardian, this documentation is required only of one legal guardian. In the alternative, documentation showing that the minor is considered emancipated under applicable State law. In accordance with § 110.83(b), the Program reserves the right to waive the requirement of documentation of guardianship for good cause.

(b) For an eligible requester who is an adult who lacks legal capacity to receive payment of benefits:

(1) Documentation showing that the requester is an adult who lacks this legal capacity (*e.g.*, declaration of legal incapacity issued by a court of competent jurisdiction, or comparable documentation); and

(2) A decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the requester's estate under applicable State law, or durable power of attorney, if applicable.

In accordance with § 110.83(b), the Program reserves the right to waive this requirement for good cause.

Subpart H—Secretarial Determinations

§ 110.70 Determinations the Secretary must make before benefits can be paid.

Before the Secretary will pay benefits under this Program, she must determine that:

(a) The requester or his or her representative submitted a completed and signed Request Form within the governing filing deadline; and

(b) The requester meets the eligibility requirements set out in this part (including a determination that a covered injury was sustained); and

(c) The requester is entitled to receive benefits from the Program. In making this determination, the Secretary will decide the type(s) and amounts of benefits that will be paid to the requester.

§ 110.71 Insufficient documentation for eligibility and benefits determinations.

In the event that there is insufficient documentation in the Request Package for the Secretary to make the applicable determinations under this part, the Secretary will so notify the requester, or his or her representative. The requester will be given 60 calendar days from the date of the Secretary's notification to submit the required documentation. If the requester is unable to provide the additional documentation, he or she may provide a written explanation of the reason(s) that the requested documentation is unavailable and the efforts the requester has made to obtain the documents. The Secretary may accept such a statement in place of the required documentation or disapprove the Request for Benefits due to insufficient documentation. If insufficient documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the Request for Benefits.

§ 110.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to evaluate a requester's eligibility, she will begin the review to determine whether the requester is eligible for Program benefits. If the Secretary determines that the requester is not eligible, the Secretary will inform the requester (or his or her representative) in writing of the disapproval, and the right to reconsideration of the determination, as described in subpart J.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, she will, after receiving adequate documentation from the requester for a benefits determination, either calculate the amount and types of benefits, as described in subpart I of this part, or request additional documentation in order to calculate the benefits that can be paid (e.g., an Explanation of Benefits from the requester's health insurance company, if none was submitted). As provided in subpart J, requesters have the right to reconsideration of the Secretary's determination of the category and amount of benefits payable under the Program.

(c) *Additional documentation required.* At any time after a Request Form has been filed, the Secretary may ask a requester to supplement or amend the Request Package by providing additional information or documentation.

§ 110.73 Approval of benefits.

When the Secretary has determined that benefits will be paid to a requester and has calculated the type and amount of such benefits, she will so notify the requester (or his or her representative) in writing. The Secretary will make payments in accordance with § 110.83. Once all benefits have been paid, the Request Package can no longer be amended (except for survivor benefits). The payment determination will constitute final agency action with regard to the particular countermeasure injury that is the subject of the Request for Benefits and payment (i.e., the Request for Benefits is closed with regard to the injury that is the basis of the payment of benefits).

§ 110.74 Disapproval of benefits.

(a) If the Secretary determines that a requester is not eligible for payments under the Program, the Secretary will disapprove the Request for Benefits and provide the requester, or his or her representative, with written notice of the basis for the disapproval, and the right to reconsideration of the determination, as provided in § 110.90.

(b) The Secretary may disapprove a Request for Benefits even before the requester has submitted all the required documentation (e.g., the Secretary may determine that a requester did not meet the filing deadline, or that a covered countermeasure was not used or administered).

(c) The Secretary may re-open a disapproved Request for Benefits on her own accord should medical or scientific evidence later become available to justify a re-determination of the

disapproval of eligibility or payments. In extraordinary circumstances, to be determined at the Secretary's discretion, she may re-open a disapproved Request for Benefits even after the requester has exercised the right to reconsideration and the disapproval determination has been upheld in accordance with the procedures set out in § 110.90.

Subpart I—Calculation and Payment of Benefits

§ 110.80 Calculation of medical benefits.

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for reasonable and necessary medical items and services to diagnose or treat a countermeasure recipient's covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31. The Secretary will consider and may rely upon benefits documentation submitted by the requester (e.g., bills, Explanation of Benefits, and cost-related documentation to support the expenses relating to the covered injury or its health complications), as required by § 110.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payer and only if no third-party payer had or has an obligation to pay for or provide such services or items to the requester, except as provided in §§ 110.83(c) and 110.84. There are no caps on the benefits for reasonable and necessary medical expenses that may be provided under the Program.

§ 110.81 Calculation of benefits for lost employment income.

(a) *Primary calculation.* Benefits under this section may be paid for days of work lost as a result of a covered injury or its health complications if the injured countermeasure recipient lost employment income for the lost work days as reasonable based on the degree of injury or disability. As stated in § 110.32(c), days for which an individual used paid leave will be considered days of work for which employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days;

(1) The Secretary will calculate the rate of benefits to be paid for the lost work days based on the injured countermeasure recipient's gross employment income, which includes

income from self-employment, at the time he or she sustained the covered injury. The Secretary may not, except with respect to injured individuals who are minors, consider projected future earnings in this calculation.

(i) For an injured countermeasure recipient with no dependents at the time the covered injury was sustained, the benefits are 66⅔ percent of the individual's gross employment income at the time of injury.

(ii) For an injured countermeasure recipient with one or more dependents at the time the covered injury was sustained, the benefits are 75 percent of the individual's gross employment income at the time of injury; and

(iii) In the case of an injured countermeasure recipient who is a minor, the Secretary may consider the provisions of 5 U.S.C. 8113 (authorizing the FECA Program), and any implementing regulations, in determining the amount of payments under this section and the circumstances under which such payments are reasonable and necessary.

(b) *Adjustment for inflation.* Benefits for lost employment income paid under the Program that represent future lost employment income will be adjusted annually to account for inflation.

(c) *Limitations on benefits paid.* The Secretary will reduce the benefits calculated under paragraphs (a) and (b) of this section according to the limitations described in this paragraph (c):

(1) *Number of lost work days.* An injured countermeasure recipient will be compensated for ten or more days of work lost if he or she lost employment income for those days as a result of the covered injury (or its health complications). If the number of days of lost employment income due to the covered injury (or its health complications) is fewer than ten, the Secretary will reduce the number of lost work days by five days. If the injured countermeasure recipient lost employment income for a period of five days or fewer, no benefits for lost employment income will be paid. Lost work days do not need to be consecutive. Partial days of lost employment income may be aggregated to calculate the total number of lost work days. The Secretary has the discretion to consider the reasonableness of the number of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation, and to consider alternative work schedules in determining the number of work days lost.

(2) *Annual limitation.* The maximum amount that an injured countermeasure recipient may receive in any one year in benefits for lost employment income under this Program is \$50,000.

(3) *Lifetime limitation.* The maximum amount that an injured countermeasure recipient can receive during his or her lifetime in benefits for lost employment income under this Program is the amount of the death benefit calculated under the PSOB Program in the same fiscal year as the year in which this lifetime cap is reached. This amount is the maximum death benefit payable to survivors under this Program using the standard calculation described in § 110.82(b). However, this lifetime cap does not apply if the Secretary determines that the countermeasure recipient has a covered injury (or injuries) meeting the definition of "disability" in section 216(i) of the Social Security Act, 42 U.S.C. 416(i).

(4) *Termination of payments.* The Secretary will not pay benefits for lost employment income after the injured countermeasure recipient reaches the age of 65.

(d) *Reductions for other coverage.* From the amount of benefits calculated under paragraphs (a), (b), and (c) of this section, the Secretary will make reductions:

(1) For all payments made, or expected to be made in the future, to the injured countermeasure recipient for compensation of lost employment income or disability or retirement benefits, by any third-party payer in relation to the covered injury or its health complications, consistent with § 110.32(b); and

(2) So that the total amount of benefits for lost employment income paid to an injured countermeasure recipient under this Program, together with the total amounts paid (or payable) by third-party payers, as described in paragraph (d)(1) of this section, does not exceed $66\frac{2}{3}$ percent (or 75 percent, if the injured countermeasure recipient had at least one dependent at the time the covered injury was sustained) of his or her employment income at the time of the covered injury for the lost work days.

(3) If an injured countermeasure recipient receives a lump-sum payment from any third-party payer under any obligation described in paragraph (d)(1) of this section, the Secretary shall consider such a payment to be received over a period of years, rather than in a single year. The Secretary has discretion as to how to apportion such payments over multiple years.

§ 110.82 Calculation of death benefits.

(a) *General.* (1) If the legal guardian(s) of dependents younger than 18 years of age does not file a written selection to receive death benefits under the alternative calculation, as described in paragraph (c)(1) of this section, or if the Secretary does not approve such a selection, the Secretary will pay proportionate death benefits under the standard calculation to all of the eligible survivors with priority to receive death benefits under the standard calculation, as described in § 110.33(b) and paragraph (b) of this section.

(2) If the Secretary approves a written selection to receive benefits under the alternative calculation, as described in paragraph (c)(1) of this section:

(i) If no other eligible survivors are of equal priority to receive death benefits, the Secretary will pay a death benefit in an amount calculated under the alternative calculation to the aggregate of the dependents on whose behalf the election was filed; and

(ii) If other eligible survivors are of equal priority to receive death benefits as the dependents receiving death benefits under the alternative calculation, the Secretary will pay the other eligible survivors a proportionate amount of the death benefit available and calculated under the standard calculation. In such circumstances, the Secretary will pay the aggregate of the dependents receiving a death benefit under the alternative calculation a proportionate share of the benefits available under that calculation (in place of the proportionate share of the death benefit that would be available under the standard calculation). For example, if a deceased countermeasure recipient is survived by a dependent ten year-old child and a spouse who is not the child's legal guardian (e.g., the dependent child's parents were the deceased injured countermeasure recipient and his or her former spouse), the current surviving spouse would be able to receive his or her share of the death benefit under the standard calculation, and the dependent child's legal guardian, on behalf of the minor, would receive either the child's proportionate share of the death benefit under the standard calculation or the child's proportionate share of the death benefit available under the alternative calculation (if the legal guardian filed a written selection for such a death benefit and the Secretary approved the selection).

(b) *Standard calculation of death benefits.* (1) The maximum death benefit available under the standard calculation of death benefits (described in this paragraph) is the amount of the

comparable death benefit calculated under the PSOB Program in the same fiscal year in which the injured countermeasure recipient died (regardless of whether the PSOB Program reduces the amount of its death benefits because of a limit in appropriations).

(2) No death benefit will be paid under the standard calculation if a death benefit is paid, or if survivors are eligible to receive a death benefit, under the PSOB Program with respect to the deceased injured countermeasure recipient.

(3) The death benefit will not be reduced under the standard calculation if a total and permanent disability benefit has been, or will be paid under the PSOB Program with respect to the deceased injured countermeasure recipient. However, the death benefit will be reduced if a temporary and partial disability benefit has been, or will be paid under the PSOB Program with respect to that individual. If the PSOB Program disability benefit paid was reduced because of a limitation on appropriations, a death benefit will be available under the standard calculation to the extent necessary to ensure that the total amount of disability benefits paid under the PSOB Program, together with the amount of death benefits paid under the standard calculation, equals the amount of the death benefit described in paragraph (b)(1) of this section.

(4) Under the standard calculation, death benefits will be paid in a lump sum.

(c) *Alternative calculation of death benefits available to surviving dependents younger than the age of 18.* If a deceased countermeasure recipient had at least one dependent who is younger than the age of 18 (and will be younger than the age of 18 at the time of the payment), the legal guardian(s) of all such dependents may request benefits under the alternative calculation described in this paragraph. To receive such a benefit, the legal guardian, on behalf of all such dependents for whom he or she is the legal guardian, must file a selection to receive benefits under the alternative calculation, as described in paragraph (c)(1) of this section, and the Secretary must approve such selection. If multiple dependents have different legal guardians, each legal guardian is responsible for requesting benefits under the standard calculation or for filing a selection for a death benefit under the alternative calculation. If a single dependent has more than one legal guardian, one legal guardian may file the selection. Payments made under

the alternative calculation will be made to the legal guardian(s) of all of the dependents on behalf of all of those dependents until they reach the age of 18.

(1) *Selection of benefits under the alternative calculation.* Before a payment of a death benefit will be approved under the alternative calculation, the legal guardian(s) of the dependents for whom he or she is the legal guardian must file a written selection, on behalf of all such dependents, to receive a death benefit under the alternative calculation. If such a selection is approved by the Secretary, these dependents will be paid a proportionate share of the death benefit under the alternative calculation in place of the proportionate share of benefits that would otherwise be available to them under the standard calculation.

(2) *Amount of payments.* The maximum death benefit available under this paragraph is 75 percent of the deceased injured countermeasure recipient's income (including income from self-employment) at the time he or she sustained the covered injury that resulted in death, adjusted to account for inflation, except as follows:

(i) The maximum payment of death benefits that may be made on behalf of the aggregate of the dependents in any one year is \$50,000;

(ii) All payments made under this paragraph will stop once the youngest of the dependents reaches the age of 18.

(3) *Reductions for other coverage.* The total amount of death benefits provided under the alternative calculation (described in this paragraph) will be reduced so that the total amount of payments made (or expected to be made) under obligations described in paragraph (c)(3)(i) of this section, together with the death benefits paid under the alternative calculation, is not greater than the amount of payments described in paragraph (c)(2) of this section. In other words, the total amount of death benefits paid to dependents under the alternative calculation may be reduced if third-party payers have paid (or are expected to pay) for certain benefits so that such dependents will receive a total sum (combining the death benefit under the alternative calculation and the actual and expected benefits covered by third-party payers) that is not greater than the death benefit that would be available under the alternative calculation if there were no third-party payer(s) to pay such benefits. The total amount of death benefits will *not* be reduced by lost employment income paid by the Program.

(i) The amount of death benefits paid under the alternative calculation will be reduced for all payments made, or expected to be made in the future, by any third-party payer for:

(A) Compensation for the deceased countermeasure recipient's loss of employment income on behalf of the dependents or their legal guardian(s) (but not any lost employment income benefits paid by the Program);

(B) Disability, retirement, or death benefits in relation to the deceased countermeasure recipient (including, but not limited to, death and disability benefits under the PSOB Program) on behalf of the dependents or their legal guardian(s); and

(C) Life insurance benefits on behalf of the dependents;

(4) *Timing of payments.* Payments made under this paragraph will be made on an annual basis, beginning from the time of the initial payment, to the legal guardian(s) on behalf of the aggregate of the dependents receiving the payment. In the year in which the youngest dependent reaches the age of 18, payments under this section will be paid on a *pro rata* basis for the period of time before that dependent reaches the age of 18. Once a dependent reaches the age of 18, the payments under this alternative calculation will no longer be made on his or her behalf. Because payments under the alternative calculation are to be made on behalf of dependents who are younger than the age of 18, if a dependent meets this requirement at the time of filing of the Request Form, but reaches the age of 18 (or is older than 18 years of age) at the time of the initial payment, no payment will be made to the dependent's legal guardian on his or her behalf under the alternative calculation.

§ 110.83 Payment of all benefits.

(a) The Secretary determines the mechanism of payment of Program benefits. She may choose to pay any benefits under this Program through lump-sum payments. If the Secretary determines that there is a reasonable likelihood that the payments of medical benefits, benefits for lost employment income, or death benefits paid under the alternative calculation (described in § 110.82(c)) will be required for a period in excess of one year from the date the Secretary determines the requester is eligible for such benefits, payments may be made through a lump-sum payment, the purchase of an annuity or medical insurance policy, establishment of a trust (including a U.S. grantor reversionary trust) or execution of an appropriate structured settlement agreement, at the Secretary's discretion.

Payments, annuities, policies, or agreements must be actuarially determined to have a value equal to the present value of the projected total amount of benefits that the requester is eligible to receive under §§ 110.80, 110.81, and 110.82. Lump sum payments will be made through an electronic funds transfer to an account of the requester.

(b) If the requester is a minor, the payment will be made on the minor's behalf to the account of the legal guardian of the estate or property of the minor. In accepting such payments, the legal guardian of a minor requester is obligated to use the funds for the benefit of the minor and to take any actions necessary to comply with State law requirements pertaining to such payments. If the requester is an adult who lacks the legal capacity to receive payment(s), the legal guardian must establish a guardianship or conservatorship of the estate account with court oversight, in accordance with State law, and payment will be made to that account. Documentation of guardianship (or conservatorship) is required for requesters who are minors or adults who lack legal capacity unless the Secretary waives this requirement for good cause.

(c) The Secretary has the discretion to make interim payments of benefits under this Program, even before a final determination as to the type(s) and total amount of benefits that will be paid. Interim payments will be made only in exceptional cases. The Secretary may, for example, make an interim payment of medical benefits that have been calculated before a final determination on benefits for lost employment income is completed, or of past medical benefits that have been calculated before a final calculation of future medical benefits is completed. The Secretary may make an interim payment even before a final eligibility or benefits determination is made (e.g., if a piece of documentation has not been obtained because a person with a severe countermeasure-related injury is hospitalized, but all other documentation is consistent with the requester meeting the eligibility requirements). If such a requester's documentation is incomplete, the requester must submit the required documentation within the time-frame determined by the Secretary. The requester must agree that he or she will be obligated to repay the Secretary such benefits in the event that a Program payment is later determined to be incorrect. Any payments made on an interim basis will not entitle a requester to seek reconsideration of the Secretary's decision on these benefits

until the Secretary makes a final benefits determination.

§ 110.84 The Secretary's right to recover benefits paid under this Program from third-party payers.

Upon payment of benefits under this Program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payer with a legal or contractual obligation to pay for (or provide) such benefits and may recover from such third-party payer(s) the amount of benefits paid up to the amount of benefits the third-party payer has or had an obligation to pay for (or provide). In other words, the Secretary may pay benefits before the requester receives a payment from a third-party payer in certain circumstances. In those circumstances, the Secretary has a right to be reimbursed by the third-party payer. The circumstances in which the Secretary may assert this right include those in which the Secretary pays benefits under this Program to a requester before a final decision is made that a third-party payer has an obligation to pay such benefits to the requester. Requesters receiving benefits under this Program (or their representatives) shall assist the Secretary in recovering such benefits. In the event that a requester receives a benefit from a third-party payer after receiving the same type of benefits from the Secretary under this Program, the Secretary has a right to recover from the requester the amount of the benefit(s) received. The requester must notify and reimburse the Program within ten business days of receiving the third-party payment(s).

Subpart J—Reconsideration of the Secretary's Determinations

§ 110.90 Reconsideration of the Secretary's eligibility and benefits determinations.

(a) *Right of reconsideration.* A requester has the right to seek reconsideration of the Secretary's determination that he or she is not eligible for Program benefits. In addition, a requester who asserts that the amount of the benefits paid (or the fact that certain benefits were not paid or payable) is incorrect may also seek reconsideration. A requester may not seek reconsideration of the Secretary's decision as to the mechanism of

payment. Requests for reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of the Secretary's decision on the Request for Benefits. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the Secretary at the time of her determination.

(b) *Letters seeking reconsideration.* A requester, or his or her representative, may send the letter seeking reconsideration through the U.S. Postal Service, commercial carrier, or a private courier service. The Secretary will not accept reconsideration requests delivered by hand. Electronic submissions of letters seeking reconsideration are not currently accepted, but may be accepted in the future. The Program will publish a notice if an electronic method becomes available. Letters sent through the U.S. Postal Service, commercial carrier or private courier service must be sent to the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12-105, Rockville, Maryland 20857.

(c) *Reconsideration process.* When the Associate Administrator of the Healthcare Systems Bureau (the Associate Administrator), receives a request for reconsideration, a qualified panel, independent of the Program, will be convened to review the Secretary's determination. The panel will base its recommendation on the documentation before the Secretary when the determination was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to the requester (or his or her representative). This will be the Secretary's final action on the request for reconsideration and will be considered the Secretary's final determination on the request for Program benefits with regard to the injury that is the subject of that Request Package. Requesters may not seek review of a decision made on reconsideration.

(d) *Effect of reconsideration on amending a Request Package.* As stated in § 110.46, a Request Package cannot be amended after exhaustion of the reconsideration process, except for amendments by survivors seeking death benefits or executors or administrators on behalf of an estate.

§ 110.91 Secretary's review authority.

Under section 319F-4(b)(4) of the Public Health Service Act (42 U.S.C. 247d-6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), the Secretary may, at any time, on her own motion or on application, review any determination made under this part (including, but not limited to, determinations concerning eligibility, entitlement to benefits, and the calculation of amount of benefits under the Program). Upon review, the Secretary may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.

§ 110.92 No additional judicial or administrative review of determinations made under this part.

(a) Under section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), no judicial review of the Secretary's actions concerning eligibility and benefits determinations under this part (including, but not limited to, determinations concerning eligibility, the type or amount of benefits, and the method of payment of benefits) is permitted. In addition, no further administrative review of such actions are permitted unless the President specifically directs otherwise.

(b) Under section 319F-4(b)(5)(c) of the PHS Act (42 U.S.C. 247d-6e(b)(5)(c)), no judicial review of the Secretary's actions in establishing or amending a Table (or Tables) for purposes of this part (which include, but are not limited to, identifying injuries on a Table (or choosing not to identify injuries on a Table), establishing time-frames or definitions for Table injuries, and amending a Table) is permitted.

Subpart K—Covered Countermeasures Injury Tables

§ 110.100 [Reserved]

[FR Doc. 2010-25110 Filed 10-14-10; 8:45 am]

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Federal Register

**Friday,
October 15, 2010**

Part V

The President

**Proclamation 8583—National School
Lunch Week, 2010**

Proclamation 8584—Columbus Day, 2010

Presidential Documents

Title 3—

Proclamation 8583 of October 8, 2010

The President

National School Lunch Week, 2010

By the President of the United States of America

A Proclamation

No child should have to learn on an empty stomach. Nearly 65 years ago, America made protecting the health of our children a national priority by developing the National School Lunch Program. This groundbreaking program has prevented hunger and promoted education by enabling our young people to have access to safe, balanced, and affordable meals at school. It has also supported their development, encouraged their learning capacity, and instilled life-long healthy habits. This year, during National School Lunch Week, we recognize the vital importance of this historic program, and we recommit to serving meals that will contribute to the health and well-being of a new generation.

With more than 31 million children participating in the National School Lunch Program and more than 11 million in the School Breakfast Program, good nutrition at school is more vital than ever. When one in three children in this country is overweight or obese, we all have a responsibility to make sure our kids receive good nutrition at school and learn to make healthy choices early in life. This is an essential part of First Lady Michelle Obama's "Let's Move!" initiative, which is a nationwide campaign dedicated to ending the epidemic of childhood obesity within a generation so that children can reach adulthood at a healthy weight.

To foster school environments that encourage physical activity and nourishing diets, "Let's Move!" is partnering with the United States Department of Agriculture (USDA) to increase the number of schools that participate in the HealthierUS School Challenge. The Challenge establishes rigorous standards for nutritional quality in school food, participation in meal programs, physical activity, and nutrition education—all key components that make for healthy, active children.

Chefs across America are also helping create nutritious and appealing school meals. Over 1,900 have volunteered to offer their unique talents and knowledge of food and nutrition to "Chefs Move to Schools," an initiative that pairs chefs with interested schools in their communities. Together, chefs and school administrators are creating wholesome meals while teaching young people about nutrition and making balanced, healthy choices. I invite all Americans to visit LetsMove.gov to learn more about this initiative and other strategies to raise a healthier generation of kids.

To provide more fruits, vegetables, and other fresh and nutritious foods for school meals, the USDA is also working to develop farm-to-school partnerships with local farmers, States, localities, tribal authorities, school districts, and community organizations. The USDA Farm to School Team is helping to provide quality foods in school menus, to increase markets for local farms, and to teach young people of all ages about the source of the food they enjoy. To enable school cafeterias across our Nation to prepare these healthy foods, the American Recovery and Reinvestment Act funded the purchase of new food service equipment such as salad bars, and the replacement of aging or outdated appliances such as deep fryers.

This week provides us with an opportunity to reflect on the critical role the National School Lunch Program plays in promoting the health and well-being of tomorrow's leaders. We also recognize the talent and dedication of all the food service professionals, educators, program administrators, and parents whose time and energy help ensure America's students have the healthy food necessary to grow and succeed.

The Congress, by joint resolution of October 9, 1962 (Public Law 87-780), as amended, has designated the week beginning on the second Sunday in October each year as "National School Lunch Week," and has requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim the week of October 10 through October 16, 2010, as National School Lunch Week. I call upon all Americans to join the dedicated individuals who administer the National School Lunch Program in appropriate activities that support the health and well-being of our Nation's children.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord two thousand ten, and of the Independence of the United States of America the two hundred and thirty-fifth.

A handwritten signature in black ink, appearing to be "Barack Obama", written in a cursive style. The signature is positioned to the right of the text of the proclamation.

Presidential Documents

Proclamation 8584 of October 8, 2010

Columbus Day, 2010

By the President of the United States of America

A Proclamation

Over five centuries ago, Christopher Columbus set sail across the Atlantic Ocean in search of a new trade route to India. The findings of this explorer from Genoa, Italy, would change the map of the world and forever alter the course of human history.

When Columbus's crewmembers came ashore in the Americas, they arrived in a world previously unknown to his contemporaries in Europe. Columbus returned to the Caribbean three more times after his maiden voyage in 1492, convinced of the vast potential of what he had seen. His expeditions foreshadowed the journey across the seas for millions of courageous immigrants who followed. As they settled, they joined indigenous communities with thriving cultures. Today, we reflect on the myriad contributions tribal communities have made to our Nation and the world, and we remember the tremendous suffering they endured as this land changed.

For more than 500 years, women and men from every corner of the globe have embarked on journeys to our shores as did Columbus. Some have sought refuge from religious or political oppression, and others have departed nations ravaged by war, famine, or economic despair. Columbus charted a course for generations of Italians who followed his crossing to America. As Italy marks the 150th anniversary of its unification this year, we celebrate the incalculable contributions of Italian Americans, whose determination, hard work, and leadership have done so much to build the strength of our Nation.

What Columbus encountered over half a millennia ago was more than earth or continent. His epic quest into the unknown may not have revealed the new trade route he sought, but it exposed the boundless potential of a new frontier. It is this intrepid character and spirit of possibility that has come to define America, and is the reason countless families still journey to our shores.

In commemoration of Christopher Columbus' historic voyage 518 years ago, the Congress, by joint resolution of April 30, 1934, and modified in 1968 (36 U.S.C. 107), as amended, has requested the President proclaim the second Monday of October of each year as "Columbus Day."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim October 11, 2010, as Columbus Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities. I also direct that the Flag of the United States be displayed on all public buildings on the appointed day in honor of Christopher Columbus.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord two thousand ten, and of the Independence of the United States of America the two hundred and thirty-fifth.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by a circle and a vertical line through it, and a horizontal line extending to the right.

Reader Aids

Federal Register

Vol. 75, No. 199

Friday, October 15, 2010

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| | |
|---|---------------------|
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| 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 |
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FEDERAL REGISTER PAGES AND DATE, OCTOBER

| | |
|------------------|----|
| 60567-61034..... | 1 |
| 61034-61320..... | 4 |
| 61321-61588..... | 5 |
| 61589-61974..... | 6 |
| 61975-62294..... | 7 |
| 62295-62448..... | 8 |
| 62449-62674..... | 12 |
| 62675-63038..... | 13 |
| 63039-63378..... | 14 |
| 63379-63694..... | 15 |

CFR PARTS AFFECTED DURING OCTOBER

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 | 73..... | 62330, 62695 |
| | 429..... | 61361 |
| | 433..... | 63404 |
| | 435..... | 63404 |
| Proclamations: | | |
| 8571..... | 62295 | |
| 8572..... | 62297 | |
| 8573..... | 62299 | |
| 8574..... | 62301 | |
| 8575..... | 62303 | |
| 8576..... | 62305 | |
| 8577..... | 62307 | |
| 8578..... | 62449 | |
| 8579..... | 62451 | |
| 8580..... | 62453 | |
| 8581..... | 63035 | |
| 8582..... | 63037 | |
| 8583..... | 63691 | |
| 8584..... | 63693 | |
| Executive Orders: | | |
| 13553..... | 60567 | |
| 13554..... | 62313 | |
| Administrative Orders: | | |
| Memorandums: | | |
| Memorandum of | | |
| September 29, | | |
| 2010..... | 61033 | |
| Memorandum of | | |
| October 4, 2010..... | 62309 | |
| 5 CFR | | |
| 870..... | 60573 | |
| 1201..... | 61321 | |
| Proposed Rules: | | |
| 831..... | 60643 | |
| 841..... | 60643 | |
| 842..... | 60643 | |
| 930..... | 61998 | |
| 1605..... | 63106 | |
| 7 CFR | | |
| 319..... | 62455 | |
| 1219..... | 61589 | |
| Proposed Rules: | | |
| 6..... | 62692 | |
| 205..... | 62693 | |
| 319..... | 62484 | |
| 1217..... | 61002, 61025 | |
| 9 CFR | | |
| 77..... | 60586 | |
| 10 CFR | | |
| 50..... | 61321 | |
| Proposed Rules: | | |
| 30..... | 62330 | |
| 32..... | 62330 | |
| 33..... | 62330 | |
| 34..... | 62330 | |
| 35..... | 62330 | |
| 36..... | 62330 | |
| 37..... | 62330, 62694 | |
| 39..... | 62330 | |
| 51..... | 62330 | |
| 71..... | 62330 | |
| 12 CFR | | |
| 25..... | 61035 | |
| 228..... | 61035 | |
| 345..... | 61035 | |
| 563e..... | 61035 | |
| Proposed Rules: | | |
| 560..... | 63107 | |
| 704..... | 60651 | |
| Ch. XIII..... | 61653 | |
| 13 CFR | | |
| 121..... | 61591, 61597, 61604, | |
| | 62258 | |
| 123..... | 60588 | |
| 124..... | 62258 | |
| 125..... | 62258 | |
| 126..... | 62258 | |
| 127..... | 62258 | |
| 134..... | 62258 | |
| Proposed Rules: | | |
| 107..... | 63110 | |
| 115..... | 63419 | |
| 14 CFR | | |
| 39..... | 60602, 60604, 60608, | |
| | 60611, 60614, 61046, 61337, | |
| | 61341, 61343, 61345, 61348, | |
| | 61352, 61975, 61977, 61980, | |
| | 61982, 61985, 61987, 61989, | |
| | 62319, 63039, 63040, 63042, | |
| | 63045, 63048, 63050, 63052, | |
| | 63054, 63058, 63060, 63062, | |
| | 63064 | |
| 71..... | 61609, 61610, 61611, | |
| | 61993, 62457, 62458, 62459, | |
| | 62460, 62461, 63066 | |
| 91..... | 61612 | |
| Proposed Rules: | | |
| 1..... | 62640 | |
| 39..... | 60655, 60659, 60661, | |
| | 60665, 60667, 60669, 61114, | |
| | 61361, 61363, 61655, 61657, | |
| | 61999, 62002, 62005, 62331, | |
| | 62333, 62716, 63420, 63422 | |
| 71..... | 61660 | |
| 91..... | 62640 | |
| 117..... | 62486, 63424 | |
| 120..... | 62640 | |
| 121..... | 62486, 63424 | |
| 135..... | 62640 | |
| 139..... | 62008 | |
| 15 CFR | | |
| 748..... | 62462 | |
| 772..... | 62675 | |
| 774..... | 62675 | |
| 902..... | 60868 | |

| | | | |
|------------------------|------------------------------|-----------------------------|------------------------------|
| 16 CFR | 30 CFR | 36 CFR | 67.....61358 |
| 1200.....63067 | 201.....61051 | 242.....63088 | Proposed Rules: |
| Proposed Rules: | 202.....61051 | Proposed Rules: | 67.....61371, 61373, 61377, |
| 260.....63552 | 203.....61051 | 67.....63428 | 62048, 62057, 62061, 62750, |
| 17 CFR | 204.....61051 | | 62751 |
| 44.....63080 | 206.....61051 | 37 CFR | |
| 200.....62466 | 207.....61051 | Proposed Rules: | 45 CFR |
| 241.....60616 | 208.....61051 | 201.....61116, 62345, 62488 | 162.....62684 |
| 243.....61050 | 210.....61051 | | 170.....62686 |
| Proposed Rules: | 212.....61051 | 38 CFR | |
| 39.....63113 | 217.....61051 | 3.....61356, 61995 | 46 CFR |
| 140.....63113 | 218.....61051 | 17.....61621 | 389.....62472 |
| 229.....62718 | 219.....61051 | Proposed Rules: | 47 CFR |
| 240.....62718 | 220.....61051 | 1.....63120 | 1.....62924 |
| 249.....62718 | 227.....61051 | 2.....63120 | 2.....62924 |
| 18 CFR | 228.....61051 | 17.....62348 | 15.....62476, 62924 |
| 806.....60617 | 229.....61051 | | 25.....62924 |
| 808.....60617 | 241.....61051 | 40 CFR | 73.....62690, 62924, 63402 |
| Proposed Rules: | 243.....61051 | 52.....60623, 62323, 62470 | 79.....61101 |
| 35.....62023 | 250.....63346, 63610 | 112.....63093 | 90.....62924 |
| 260.....61365 | 290.....61051 | 156.....62323 | Proposed Rules: |
| 19 CFR | 1201.....61051 | 261.....60632, 61356 | 73.....63431 |
| Proposed Rules: | 1202.....61051 | Proposed Rules: | 48 CFR |
| 210.....60671 | 1203.....61051 | 26.....62738 | Proposed Rules: |
| 20 CFR | 1204.....61051 | 52.....61367, 61369, 62024, | 25.....62069 |
| 404.....62676 | 1206.....61051 | 62026, 62354, 63139 | 216.....60690 |
| 416.....62676 | 1207.....61051 | 60.....63260 | 252.....60690 |
| Ch. VI.....63379 | 1208.....61051 | 63.....61662 | |
| Proposed Rules: | 1210.....61051 | 81.....60680, 62026 | 49 CFR |
| 404.....62487 | 1212.....61051 | 85.....62739 | 395.....61626 |
| 405.....62487 | 1217.....61051 | 86.....62739 | 593.....62482 |
| 416.....62487 | 1218.....61051 | 122.....62358 | Proposed Rules: |
| 655.....61578 | 1219.....61051 | 261.....60689, 62040 | 227.....61386 |
| 701.....63425 | 1220.....61051 | 300.....63140 | 531.....62739 |
| 21 CFR | 1227.....61051 | 600.....62739 | 533.....62739 |
| 522.....62468 | 1228.....61051 | 41 CFR | |
| 529.....63085 | 1229.....61051 | Ch. 301.....63103 | 50 CFR |
| 1306.....61613 | 1241.....61051 | 301-10.....63103 | 17.....62192 |
| 22 CFR | 1243.....61051 | 301-11.....63103 | 18.....61631 |
| Proposed Rules: | 1290.....61051 | 301-50.....63103 | 100.....63088 |
| 62.....60674 | Proposed Rules: | 301-73.....63103 | 600.....62326 |
| 24 CFR | 56.....62024 | 42 CFR | 635.....62690 |
| Proposed Rules: | 57.....62024 | 110.....63656 | 660.....60868, 61102 |
| 203.....62335 | 926.....61366 | 412.....60640 | 679.....61638, 61639, 61642, |
| 26 CFR | 31 CFR | 413.....60640 | 62482, 63104, 63402 |
| 1.....63380 | 1.....61994 | 415.....60640 | Proposed Rules: |
| 28 CFR | 103.....63382 | 424.....60640 | 17.....61664, 62070 |
| Proposed Rules: | Proposed Rules: | 440.....60640 | 21.....60691 |
| 2.....62342 | 1.....62737 | 441.....60640 | 217.....60694 |
| 29 CFR | 32 CFR | 482.....60640 | 223.....61872 |
| 4022.....63380 | 199.....63383 | 485.....60640 | 224.....61872, 61904 |
| | 323.....61617 | 489.....60640 | 226.....61690 |
| | 701.....61618 | 43 CFR | 622.....62488 |
| | 33 CFR | 3100.....61624 | 660.....60709 |
| | 117.....61094, 62468, 62469, | 44 CFR | |
| | 63086, 63398 | 64.....63399 | |
| | 165.....61096, 61099, 61354, | | |
| | 61619, 62320, 63086 | | |

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-741-6043. This list is also available online at <http://www.archives.gov/federal-register/laws.html>.

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Office, Washington, DC 20402 (phone, 202-512-1808). The text will also be made available on the Internet from GPO Access at <http://www.gpoaccess.gov/plaws/index.html>. Some laws may not yet be available.

H.R. 2923/P.L. 111-268
Combat Methamphetamine Enhancement Act of 2010 (Oct. 12, 2010; 124 Stat. 2847)

H.R. 3553/P.L. 111-269
Indian Veterans Housing Opportunity Act of 2010 (Oct. 12, 2010; 124 Stat. 2850)

H.R. 3689/P.L. 111-270
To provide for an extension of the legislative authority of the Vietnam Veterans Memorial

Fund, Inc. to establish a Vietnam Veterans Memorial visitor center, and for other purposes. (Oct. 12, 2010; 124 Stat. 2851)

H.R. 3980/P.L. 111-271

Redundancy Elimination and Enhanced Performance for Preparedness Grants Act (Oct. 12, 2010; 124 Stat. 2852)

S. 1132/P.L. 111-272

Law Enforcement Officers Safety Act Improvements Act of 2010 (Oct. 12, 2010; 124 Stat. 2855)

S. 3397/P.L. 111-273

Secure and Responsible Drug Disposal Act of 2010 (Oct. 12, 2010; 124 Stat. 2858)

Last List October 14, 2010

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