

Journal of  
Neuroscience



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# Contents

## Federal Register

Vol. 64, No. 202

Wednesday, October 20, 1999

### Agriculture Department

See Animal and Plant Health Inspection Service  
 See Farm Service Agency  
 See Food and Nutrition Service  
 See Food Safety and Inspection Service  
 See Rural Business-Cooperative Service  
 See Rural Housing Service  
 See Rural Utilities Service

### Animal and Plant Health Inspection Service

#### RULES

Interstate transportation of animals and animal products (quarantine):  
 Tuberculosis in cattle and bison—  
 State and area classifications, 56399–56400

### Architectural and Transportation Barriers Compliance Board

#### NOTICES

Committees; establishment, renewal, termination, etc.:  
 Public Rights-of-Way Access Advisory Committee; meeting, 56482–56483

### Arts and Humanities, National Foundation

See National Foundation on the Arts and the Humanities

### Bonneville Power Administration

#### NOTICES

Environmental statements; notice of intent:  
 Columbia River Basin; fish and wildlife implementation plan, 56488–56489

### Children and Families Administration

#### NOTICES

Agency information collection activities:  
 Submission for OMB review; comment request, 56508–56509

### Commerce Department

See Export Administration Bureau  
 See International Trade Administration  
 See National Oceanic and Atmospheric Administration  
 See Patent and Trademark Office

### Customs Service

#### RULES

Financial and accounting procedures:  
 Customs duties, taxes, fees and interest; underpayments and overpayments interest, 56433–56441

#### NOTICES

Agency information collection activities:  
 Proposed collection; comment request, 56573–56577

### Education Department

#### RULES

Postsecondary education:  
 Secretary's recognition of accrediting agencies, 56611–56626

#### NOTICES

Special education and rehabilitative services:  
 Individuals with Disabilities Education Act (IDEA)—  
 Correspondence; quarterly list, 56645–56647

### Energy Department

See Bonneville Power Administration  
 See Federal Energy Regulatory Commission

#### RULES

Assistance regulations:  
 Technical and administrative amendments, 56418–56420

#### NOTICES

Committees; establishment, renewal, termination, etc.:  
 Fusion Energy Sciences Advisory Committee, 56488

### Environmental Protection Agency

#### RULES

Hazardous waste:  
 Land disposal restrictions—  
 Wood preserving wastes, metal wastes, zinc micronutrient fertilizers, etc.; correction, 56469–56472

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:  
 Pyrethrin sodium salt, 56464–56469

#### PROPOSED RULES

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:  
 Cyromazine  
 Correction, 56477

#### NOTICES

Agency information collection activities:  
 Submission for OMB review; comment request, 56492–56493

Air pollutants, hazardous; national emission standards:  
 Source categories—  
 Surface coating; two-piece beer and beverage can coating, 56493–56496

#### Air programs:

State implementation plans; adequacy status for transportation conformity purposes—  
 Illinois, 56497–56498  
 Indiana, 56496–56497  
 Wisconsin, 56497

#### Meetings:

Environmental Policy and Technology National Advisory Council, 56498–56499

Pesticide, food, and feed additive petitions:  
 Monsanto Co., 56502–56505

Pesticide registration, cancellation, etc.:  
 American Cyanamid Co., 56499–56500  
 BOC Gases America et al., 56500–56502

#### Water pollution control:

State water quality standards; approval and disapproval lists and individual control strategies; availability—  
 Minnesota, 56505

### Executive Office of the President

See Management and Budget Office  
 See Presidential Documents  
 See Trade Representative, Office of United States

### Export Administration Bureau

#### NOTICES

Export privileges, actions affecting:  
 Thane-Coat, Inc., et al., 56483–56485

**Farm Service Agency****RULES**

Program regulations:

Community Facilities Grant Program  
Correction, 56399**Federal Aviation Administration****RULES**

Airworthiness directives:

Boeing, 56420–56422

Fokker, 56422–56424

McDonnell Douglas, 56424–56426

Saab, 56426–56428

Class E airspace, 56428–56429

**Federal Bureau of Investigation****NOTICES**

Meetings:

DNA Advisory Board, 56516

**Federal Communications Commission****NOTICES**

Meetings; Sunshine Act, 56505–56506

**Federal Election Commission****NOTICES**

Meetings; Sunshine Act, 56506

**Federal Energy Regulatory Commission****NOTICES**

Electric rate and corporate regulation filings:

Louisville Gas &amp; Electric Co. et al., 56490–56492

Environmental statements; availability, etc.:

TriState Pipeline, L.L.C., 56492

*Applications, hearings, determinations, etc.:*

Texas Eastern Transmission Corp., 56489–56490

Vector Pipeline L.P., 56490

**Federal Reserve System****NOTICES**

Federal Open Market Committee:

Domestic policy directives, 56506–56507

Meetings; Sunshine Act, 56507

**Fish and Wildlife Service****RULES**

Endangered and threatened species:

Deseret milk-vetch, 56590–56596

Devils River minnow, 56596–56609

Pecos sunflower, 56581–56590

**Food and Drug Administration****RULES**

Biological products:

Biological license implementation; establishment and  
product licenses elimination, 56441–56454

Environmental impact considerations:

Foods, food additives, and color additives; CFR  
correction, 56454**NOTICES**

Meetings:

Anti-Infective Drugs Advisory Committee, 56509

Dermatologic and Ophthalmic Drugs Advisory  
Committee, 56509–56510**Food and Nutrition Service****NOTICES**

Agency information collection activities:

Proposed collection; comment request, 56482

**Food Safety and Inspection Service****RULES**

Meat and poultry inspection:

Sanitation requirements for official establishments,  
56400–56418**Health and Human Services Department**

See Children and Families Administration

See Food and Drug Administration

See National Institutes of Health

**RULES**

Health resources development:

Organ procurement and transplantation network;  
operation and performance goals, 56649–56661**NOTICES**

Committees; establishment, renewal, termination, etc.:

Xenotransplantation Advisory Committee, 56507–56508

**Interior Department**

See Fish and Wildlife Service

See Land Management Bureau

See Minerals Management Service

See National Park Service

**Internal Revenue Service****NOTICES**

Agency information collection activities:

Proposed collection; comment request, 56577–56578

Income taxes:

Defined benefit pension plans; comment request, 56578–  
56579**International Development Cooperation Agency**

See Overseas Private Investment Corporation

**International Trade Administration****NOTICES**

Antidumping and countervailing duties:

Administrative review requests, 56485–56486

**International Trade Commission****NOTICES**

Import investigations:

Drams of one megabit and above from—

Taiwan, 56515

Neodymium-iron-boron magnets, magnet alloys, and  
articles containing same, 56515–56516**Justice Department**

See Federal Bureau of Investigation

**Labor Department****NOTICES**

Agency information collection activities:

Submission for OMB review; comment request, 56516

**Land Management Bureau****NOTICES**

Closure of public lands:

Nevada, 56514

Meetings:

Resource Advisory Councils—  
Northwest Colorado, 56514**Management and Budget Office****NOTICES**

Metropolitan and nonmetropolitan areas; definition

standards review and alternative approaches; comment  
request, 56627–56644

**Minerals Management Service****RULES**

Royalty management:

Indian leases; gas valuation; training sessions, 56454–56455

**National Archives and Records Administration****NOTICES**

Electronic copies previously covered by General Records Schedule 20; records schedules availability and comment request, 56517–56518

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

Meetings; Sunshine Act, 56518

**National Highway Traffic Safety Administration****NOTICES**

Motor vehicle safety standards:

Nonconforming vehicles—  
Importation eligibility; determinations, 56564–56570

**National Institutes of Health****NOTICES**

Meetings:

National Cancer Institute, 56510–56512  
National Heart, Lung, and Blood Institute, 56512  
National Institute of Diabetes and Digestive and Kidney Diseases, 56513  
National Institute of Neurological Disorders and Stroke, 56512  
National Institute on Drug Abuse, 56512–56513  
Women's Health Research Advisory Committee, 56513

**National Oceanic and Atmospheric Administration****RULES**

Fishery conservation and management:

Alaska; fisheries of Exclusive Economic Zone—  
Pacific cod, 56473–56475  
Pollock, 56473–56475  
Yellowfin sole, 56474  
Atlantic highly migratory species—  
Atlantic bluefin tuna, 56472–56473

**PROPOSED RULES**

Fishery conservation and management:

Alaska; fisheries of Exclusive Economic Zone—  
Pollock, 56481  
West Coast States and Western Pacific fisheries—  
Western Pacific Region pelagic species; environmental impact statement, 56479–56481

**NOTICES**

Meetings:

Mid-Atlantic Fishery Management Council et al., 56486  
New England Fishery Management Council, 56487

**National Park Service****RULES**

National Park System:

Glacier Bay National Park, AK; commercial fishing activities, 56455–56464

**Northeast Dairy Compact Commission****NOTICES**

Meetings, 56518

**Nuclear Regulatory Commission****PROPOSED RULES**

Rulemaking petitions:

Nuclear Energy Institute; withdrawn, 56476

**NOTICES**

Environmental statements; availability, etc.:

Public Service Electric & Gas Co., 56523–56524

Meetings:

Reactor Safety Goal Policy Statement; public workshop, 56524–56525

Spent nuclear fuel transportation; shipping cask accident studies, 56525–56526

Meetings; Sunshine Act, 56526

Operating licenses, amendments; no significant hazards considerations; biweekly notices, 56526–56543

*Applications, hearings, determinations, etc.:*

Niagara Mohawk Power Corp., 56518–56522

Northeast Nuclear Energy Co. et al., 56522–56523

**Office of Management and Budget**

See Management and Budget Office

**Office of United States Trade Representative**

See Trade Representative, Office of United States

**Overseas Private Investment Corporation****NOTICES**

Agency information collection activities:

Proposed collection; comment request, 56514

**Patent and Trademark Office****NOTICES**

Senior Executive Service:

Performance Review Board; membership, 56488

**Postal Service****NOTICES**

Meetings:

Consensus Committee, 56543

**Presidential Documents****PROCLAMATIONS**

*Special observances:*

Character Counts Week, National (Proc. 7242), 56663–56666

**ADMINISTRATIVE ORDERS**

Columbia; continuation of emergency with respect to significant narcotics traffickers (Notice of October 19, 1999), 56663–56667 ,

**Public Health Service**

See Food and Drug Administration

See National Institutes of Health

**Research and Special Programs Administration****NOTICES**

Meetings:

Pipeline safety; damage prevention (“path forward”), 56570–56571

**Rural Business-Cooperative Service****RULES**

Program regulations:

Community Facilities Grant Program  
Correction, 56399

**Rural Housing Service****RULES**

Program regulations:

Community Facilities Grant Program  
Correction, 56399

**Rural Utilities Service****RULES**

Program regulations:  
Community Facilities Grant Program  
Correction, 56399

**Securities and Exchange Commission****RULES**

Electronic Data Gathering, Analysis, and Retrieval  
(EDGAR):  
Filer manual—  
Update adoption and incorporation by reference,  
56430–56433

**NOTICES**

Options Price Reporting Authority:  
Participation fee payable by each new party to plan,  
56543–56545

**Securities:**

Suspension of trading—  
Las Vegas Entertainment Network, Inc., 56545  
Self-regulatory organizations; proposed rule changes:  
American Stock Exchange LLC, 56545–56547  
Chicago Board Options Exchange, Inc., 56547–56548  
Chicago Stock Exchange, Inc., 56548–56554  
National Association of Securities Dealers, Inc., 56554–  
56560  
New York Stock Exchange, Inc., 56560–56562  
Pacific Exchange, Inc., 56562–56564

**Social Security Administration****NOTICES**

Senior Executive Service:  
Performance Review Board; membership, 56564

**State Department****NOTICES**

Organization, functions, and authority delegations:  
Director General of Foreign Service and Director of  
Personnel, 56564

**Surface Transportation Board****NOTICES**

Motor carriers:  
Finance applications—  
Northwest Motor Coach L.L.C., 56571–56572  
Railroad operation, acquisition, construction, etc.:  
Delta Southern Railroad Co., 56572–56573

**Trade Representative, Office of United States****RULES**

Tariff-rate quota amount determinations:  
Lamb meat, 56429–56430

**Transportation Department**

See Federal Aviation Administration  
See National Highway Traffic Safety Administration  
See Research and Special Programs Administration  
See Surface Transportation Board

**PROPOSED RULES**

Motor carrier safety standards:  
Inspection, repair, and maintenance of intermodal  
container chassis and trailers; responsibilities;  
meeting, 56478–56479

**Treasury Department**

See Customs Service

See Internal Revenue Service

**NOTICES**

Agency information collection activities:  
Proposed collection; comment request, 56576–56577

---

**Separate Parts In This Issue****Part II**

Department of Interior, Fish and Wildlife Service, 56581–  
56609

**Part III**

Department of Education, 56611–56626

**Part IV**

Department of Management and Budget, 56627–56644

**Part V**

Department of Education, 56645–56647

**Part VI**

Department of Health and Human Services, 56649–56661

**Part VII**

The President, 56663–56667

---

**Reader Aids**

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

**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:**

7242.....56665

**Executives Orders:**12978 (See Notice of  
October 19, 1999).....56667**Administrative Orders:**Notice of October 19,  
1999.....56667**7 CFR**

2003.....56399

3570.....56399

**9 CFR**

77.....56399

303.....56400

304.....56400

307.....56400

308.....56400

312.....56400

314.....56400

327.....56400

331.....56400

350.....56400

381.....56400

416.....56400

**10 CFR**

600.....56418

**Proposed Rules:**

50.....56476

**14 CFR**39 (4 documents) .....56420,  
56422, 56424, 5642671 (2 documents) .....56428,  
56429**15 CFR**

2014.....56429

**17 CFR**

232.....56430

239.....56430

249.....56430

259.....56430

269.....56430

274.....56430

**19 CFR**

24.....56433

159.....56433

174.....56433

**21 CFR**

3.....56441

5.....56441

10.....56441

20.....56441

25.....56454

50.....56441

56.....56441

58.....56441

207.....56441

310.....56441

312.....56441

316.....56441

600.....56441

601.....56441

607.....56441

610.....56441

640.....56441

660.....56441

**30 CFR**

202.....56454

206.....56454

**34 CFR**

602.....56612

**36 CFR**

13.....56455

**40 CFR**

180.....56464

261.....56469

262.....56469

268.....56469

**Proposed Rules:**

180.....56477

**42 CFR**

121.....56650

**49 CFR****Proposed Rules:**

Ch. III.....56478

**50 CFR**

17 (3 documents) .....56582,

56590, 56596

635.....56472

679 (5 documents) .....56473,

56474, 56475

**Proposed Rules:**

660.....56479

679.....56481

# Rules and Regulations

Federal Register

Vol. 64, No. 202

Wednesday, October 20, 1999

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 AGRICULTURE

### Rural Housing Service

### Rural Business-Cooperative Service

### Rural Utilities Service

### Farm Service Agency

### 7 CFR Parts 2003 and 3570

RIN 0575-AC10

### Community Facilities Grant Program; Correction

**AGENCIES:** Rural Housing Service (RHS), Rural Business-Cooperative Service (RBS), Rural Utilities Service (RUS), and Farm Service Agency (FSA), USDA.

**ACTION:** Correction to final regulations.

**SUMMARY:** The Rural Housing Service (RHS) corrects a final rule published June 17, 1999 (64 FR 32387). This action is to remove an incorrect amendment. Accordingly, the final rule is corrected to read as follows: On page 32388 in the third column, remove Amendment 3 and redesignate remaining amendments accordingly.

**EFFECTIVE DATE:** October 20, 1999.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Barton, Senior Loan Specialist, Community Programs Division, Rural Housing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250-0787, telephone (202) 720-1504.

Dated: September 27, 1999.

**Jill Long Thompson,**

*Under Secretary Rural Development.*

[FR Doc. 99-27405 Filed 10-19-99; 8:45 am]

BILLING CODE 3410-XV-M

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 9 CFR Part 77

[Docket No. 99-063-1]

### Tuberculosis in Cattle and Bison; State Designations; California, Pennsylvania, and Puerto Rico

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the tuberculosis regulations concerning the interstate movement of cattle and bison by raising the designations of California, Pennsylvania, and Puerto Rico from modified accredited States to accredited-free States. We have determined that California, Pennsylvania, and Puerto Rico meet the criteria for designation as accredited-free States.

**DATES:** This interim rule is effective October 14, 1999. We invite you to comment on this docket. We will consider all comments that we receive by December 20, 1999.

**ADDRESSES:** Please send your comment and three copies to: Docket No. 99-063-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 99-063-1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joseph VanTiem, Senior Staff

Veterinarian, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231; (301) 734-7716.

### SUPPLEMENTARY INFORMATION:

#### Background

Bovine tuberculosis is a contagious, infectious, and communicable disease caused by *Mycobacterium bovis*. The regulations in 9 CFR part 77, "Tuberculosis" (referred to below as the regulations), regulate the interstate movement of cattle and bison because of tuberculosis. Cattle and bison not known to be affected with or exposed to tuberculosis are eligible for interstate movement without restriction if those cattle or bison are moved from a State designated as an accredited-free, accredited-free (suspended), or modified accredited State. The regulations restrict the interstate movement of cattle and bison not known to be affected with or exposed to tuberculosis if those cattle or bison are moved from a nonmodified accredited State.

The status of a State is based on its freedom from evidence of tuberculosis in cattle or bison, the effectiveness of the State's tuberculosis eradication program, and the degree of the State's compliance with the standards contained in a document titled "Uniform Methods and Rules—Bovine Tuberculosis Eradication," which has been made part of the regulations by incorporation by reference. A State must have no findings of tuberculosis in any cattle or bison for at least 5 years to be designated as an accredited-free State. A State that reverts to modified accredited status from accredited-free status, due to the detection of tuberculosis in two or more herds within a 48-month period, is eligible to apply for the reinstatement of its accredited-free status following 5 years of freedom from evidence of tuberculosis and full compliance with the standards contained in the "Uniform Methods and Rules—Bovine Tuberculosis Eradication."

Before publication of this interim rule, California, Pennsylvania, and Puerto Rico were designated in § 77.1 of the regulations as modified accredited States. However, California, Pennsylvania, and Puerto Rico now meet the requirements for designation as accredited-free States. The two States and Puerto Rico have been free of tuberculosis for at least 5 years, and



they have met the requirements of the standards contained in the "Uniform Methods and Rules—Bovine Tuberculosis Eradication" by tracing all potential sources of infection and maintaining an adequate level of slaughter surveillance. Therefore, we are amending the regulations by removing California, Pennsylvania, and Puerto Rico from the list of modified accredited States in § 77.1 and adding them to the list of accredited-free States in that section.

### Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is warranted to change the regulations so that they accurately reflect the current tuberculosis status of California, Pennsylvania, and Puerto Rico as accredited-free States. This will provide prospective cattle and bison buyers with accurate and up-to-date information, which may affect the marketability of cattle and bison since some prospective buyers prefer to buy cattle and bison from accredited-free States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make this action effective less than 30 days after publication. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

### Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

Cattle and bison are moved interstate for slaughter, for use as breeding stock, or for feeding. California has approximately 2,650 dairy herds and 12,158 beef herds with a combined total of approximately 5,968,679 cattle. Approximately 98 percent of herd owners would be considered small businesses. Pennsylvania has approximately 10,920 dairy herds and 11,237 beef herds with a combined total of approximately 1,672,295 cattle. Approximately 99 percent of herd

owners would be considered small businesses. Puerto Rico has approximately 1,982 dairy herds and 3,957 beef herds with a combined total of approximately 386,980 cattle. Approximately 99 percent of herd owners would be considered small businesses. Changing the status of California, Pennsylvania, and Puerto Rico may enhance the marketability of cattle and bison from those States, since some prospective cattle and bison buyers prefer to buy cattle and bison from accredited-free States. This may result in some beneficial economic effect on some small entities. However, based on our experience in similar designations of other States, the effect should not be significant.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

### Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

### Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

### List of Subjects in 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

Accordingly, we are amending 9 CFR part 77 as follows:

### PART 77—TUBERCULOSIS

1. The authority citation for part 77 continues to read as follows:

**Authority:** 21 U.S.C. 111, 114, 114a, 115–117, 120, 121, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 77.1, in the definition of *Accredited-free state*, paragraph (2) is amended by adding "California," immediately after "Arkansas," and by adding "Pennsylvania, Puerto Rico," immediately after "Oregon," and in the definition of *Modified accredited State*, paragraph (2) is revised to read as follows:

### § 77.1 Definitions.

\* \* \* \* \*

*Modified accredited State.*

\* \* \* \* \*

(2) Modified accredited States: New Mexico and Texas.

\* \* \* \* \*

Done in Washington, DC, this 14th day of October 1999.

**Richard L. Dunkle,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 99–27322 Filed 10–19–99; 8:45 am]

BILLING CODE 3410–34–U

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

**9 CFR Parts 303, 304, 307, 308, 312, 314, 327, 331, 350, 381, and 416**

[Docket No. 96–037F]

### Sanitation Requirements for Official Meat and Poultry Establishments

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is revising its regulatory requirements concerning sanitation in official meat and poultry establishments. Specifically, FSIS is consolidating the sanitation regulations into a single part applicable to both official meat and poultry establishments, eliminating unnecessary differences between the sanitation requirements for meat and poultry processing, and converting many of the highly prescriptive sanitation requirements to performance standards. **EFFECTIVE DATES:** January 25, 2000.

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### SUPPLEMENTARY INFORMATION:

#### Background

As a result of a recent, comprehensive review of its regulatory procedures and

requirements, FSIS identified the need to revise its sanitation requirements for official meat and poultry establishments. The Agency's tentative view was that a number of the sanitation requirements were difficult to understand, redundant, or outdated. Also, the Agency found that there were unnecessary differences between the sanitation regulations for official meat and poultry establishments. Finally, the Agency could not justify the retention of the sanitation regulations that were inconsistent with the Agency's recently finalized Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedure (Sanitation SOP) regulations. These sanitation requirements were unnecessarily prescriptive, impeded innovation, and blurred the distinction between establishment and inspection program employee responsibilities for maintaining sanitary conditions.

Therefore, on August 25, 1997, FSIS published in the **Federal Register** a proposal to revise its sanitation requirements for official meat and poultry establishments (62 FR 45045). FSIS proposed to consolidate the sanitation regulations into a single part applicable to both official meat and poultry establishments, eliminate unnecessary differences between the meat and poultry sanitation requirements, and convert many of the highly prescriptive sanitation requirements into performance standards. FSIS initially solicited comment on the proposal for a 60-day period ending October 24, 1997.

Shortly after the comment period for that proposal opened, FSIS mistakenly released information that mischaracterized the provisions of the proposal concerning the use of nonfood compounds and proprietary substances. In order to alleviate any confusion regarding the sanitation proposal and to clarify FSIS policy in regard to nonfood compounds and proprietary substances, FSIS published a retraction of the erroneous information in the **Federal Register** (FSIS Docket No. 97-062N; 62 FR 55996). Further, in order to ensure that the public had ample opportunity to submit meaningful comments on the sanitation proposal and its provisions concerning nonfood compounds and proprietary substances, FSIS reopened the comment period for that proposal for 15 days, from October 28, 1997, to November 10, 1997 (FSIS Docket 96-037R; 62 FR 55997).

By the close of the second comment period, FSIS had received 51 comments from meat and poultry establishments, trade and professional associations, academia, consumer advocacy groups,

State governments, and FSIS inspection program employees. Two of these comments included requests for a 90-day extension of the original comment period. FSIS believed the original 60-day comment period was sufficient and did not extend it, except for the 15-day period discussed above.

About two-thirds of the commenters opposed the proposal in general. Many of these commenters characterized the proposal as "deregulation" that would weaken inspection program employee authority and reduce the consumer food safety protections in the existing prescriptive regulations. Most of these commenters argued that there should be no, or only minimal, change to the existing sanitation regulations.

The other third of the commenters generally supported the proposal to revise the sanitation requirements for official meat and poultry establishments. These commenters commended FSIS efforts to streamline and consolidate the sanitation requirements, to make the requirements consistent with the HACCP and Sanitation SOP regulations, and to grant establishments greater flexibility to innovate. Many of these commenters, however, did raise objections to and recommend revisions for specific provisions in the proposed rule.

FSIS responses to all of the relevant comments follow.

#### *General Opposition*

*Comment:* Many of the commenters opposed to the proposal characterized the performance standards as "deregulation" that would weaken FSIS enforcement authority and endanger consumers. Some of these commenters maintained that the proposed performance standards are too general to be enforceable, as they would allow for multiple interpretations of the sanitation standards. Several commenters also argued that by replacing with performance standards the existing sanitation requirements that contain prohibitions against specific activities, such as the prohibition in § 308.8(e) against "placing skewers, tags, or knives in the mouth," FSIS would be impairing inspection program employees' ability to take action as necessary to prevent product adulteration.

*Response:* The sanitation performance standards are "deregulatory" in the sense that they remove obstacles to innovation previously caused by overly prescriptive, and in some cases obsolete, sanitation regulations. For establishments to fully and successfully meet the HACCP and Sanitation SOP requirements, they must be able to

innovate, or at least customize their operating procedures, to control food safety hazards and ensure that product does not become adulterated within their unique processing environments. The sanitation performance standards established in this rule not only will provide meat and poultry establishments with the flexibility to innovate in facility design, construction, and operations, but also will articulate the standards for good sanitation and for food product safety that must be met by establishments.

The sanitation performance standards are not subject to multiple interpretations. Regardless of the area or activity any individual performance standard governs, all of the sanitation standards have the same intent: An official meat or poultry establishment must operate under sanitary conditions, in a manner that ensures that product is not adulterated and that does not interfere with FSIS inspection and its enforcement of such standards. However, because the sanitation performance standards define the results to be achieved by sanitation, but not the specific means to achieve those results, the sanitation performance standards can be met by establishments in different ways. Regardless of the means by which establishments comply with the standards, the required results will be the same for all establishments.

The sanitation performance standards do not lessen the authority of FSIS inspection program employees nor in any way weaken the statutory and regulatory requirements that official meat and poultry establishments maintain sanitary conditions and ensure that product is not adulterated. Section 8 of the Federal Meat Inspection Act (FMIA) states that the "Secretary shall cause to be made by experts in sanitation or other competent inspectors, such inspection \* \* \* as may be necessary to inform himself of the sanitary conditions \* \* \* of \* \* \* establishments." It also provides that "where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, (the Secretary of Agriculture) shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as 'inspected and passed.'" Likewise section 7 of the Poultry Products Inspection Act (PPIA) requires that every official poultry establishment subject to inspection be operated according to sanitary practices "required by regulations promulgated by the Secretary (of Agriculture) for the purpose of preventing the entry into \* \* \* commerce \* \* \* of poultry

products which are adulterated" and directs the Secretary of Agriculture to refuse inspection "to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the (sanitation) requirements of this section."

FSIS does not need to specifically prohibit every action that could possibly lead to product adulteration or insanitary conditions. It would, in fact, be impossible to compile such a list of prohibited practices. FSIS inspection program employees currently have the authority to withhold the mark of inspection if an establishment fails to ensure that product is not adulterated or fails to maintain sanitary conditions, even if the failure in question is not specifically prohibited in the regulations. This authority remains unchanged under the new performance standards. For example, were an establishment employee to place a knife used on inspected product in his mouth, that action would be a violation of § 416.5(a), "All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product."

*Comment:* Several commenters objected to the proposed rescission of the regulations requiring that various systems (such as plumbing and sewage systems) and activities (such as the use of sanitizers, pesticides, and other chemicals) be prior-approved by circuit supervisors or other FSIS program employees. These commenters claimed that many serious sanitation problems can be prevented only through prior-approval of such systems and activities by experienced FSIS program employees. Further, these commenters maintained that without prior approval, establishments will negligently use pesticides and other chemicals, adulterating product.

*Response:* FSIS disagrees. In regard to the prior approval of establishment plumbing, sewage, and other systems, FSIS has made the determination that it should afford establishments the flexibility to determine what is appropriate and sufficient for maintaining sanitary conditions and preventing the adulteration of product. FSIS will verify that these systems meet the sanitation performance standards through inspection. FSIS already has rescinded the requirements for prior approval of establishment drawings, specifications, and equipment used in official establishments (62 FR 45015; August 25, 1997).

In regard to the use of pesticides, sanitizers, and other chemicals, FSIS

has determined that it is the establishment's responsibility to ensure that the chemicals it uses are safe and appropriate for use in its particular meat or poultry processing environment. Establishments will be required to account for the safety and appropriate use of these chemicals in their written HACCP plans, Sanitation SOP's, or in other documentation. A full discussion of this issue can be found below under the section entitled "Cleaning Compounds and Sanitizers."

*Comment:* Finally, two commenters argued that the proposed performance standards could have a deleterious impact on trade. One stated that European countries with more stringent sanitation requirements would ban imports of U.S. meat and poultry products if the proposed performance standards were made final.

*Response:* FSIS disagrees. Many of the United States' major agricultural trading partners have already implemented or are currently developing meat and poultry inspection systems incorporating performance standards or food safety objectives, rather than prescriptive, "command-and-control" regulations. Further, because the sanitation performance standards do not lower the existing food safety standards for meat and poultry, but instead only allow for increased flexibility and innovation to meet the prescribed standards, other countries would not be justified in imposing any new restrictions in response. Thus, FSIS anticipates that these new regulations will have no adverse impact on trade.

#### *General Sanitation: Proposed § 416.1*

*Comment:* Several commenters questioned the proposed performance standard language in § 416.1 and elsewhere requiring that establishments be operated in a sanitary manner sufficient to prevent product from being "misbranded." These commenters argued that there could never be a situation where insanitation by itself could lead to misbranding and, therefore, that the requirement is unnecessary.

*Response:* FSIS agrees that it would be highly unlikely for any meat or poultry product to be misbranded as a result of insanitation and has removed the references to misbranding from §§ 416.1, 416.2(c), and 416.3. Establishments should keep in mind, however, that the misbranding of meat or poultry products is prohibited by the FMIA, the PPIA, and the regulations promulgated under those Acts. FSIS will take action in accordance with its statutory authority and the regulations

any time it determines that meat or poultry products have been misbranded.

*Comment:* Similarly, several commenters questioned the proposed rule language requiring that establishments operate in a sanitary manner in order to prevent both "adulteration" and "contamination." These commenters argued that "contamination" is a very broad term that can describe problems with product quality or composition, as well as those associated with product safety. They maintained that a requirement to prevent "adulteration" would be sufficient, as "adulteration" is defined by both the FMIA and the PPIA.

*Response:* FSIS agrees that the term "contamination" may cause some confusion and has removed the references to "contamination" throughout the rule language. FSIS emphasizes, however, that establishments must maintain sanitary conditions within their processing facilities, as insanitary conditions do lead to the adulteration of product. While the references to "contamination" have been removed, FSIS has added to the regulations the requirement that processing activities and the use of chemicals and equipment must not create insanitary conditions.

#### *Establishment Grounds and Pest Management: Proposed § 416.2(a)*

*Comment:* Several commenters objected to the language of proposed § 416.2(a) regarding establishment grounds: "The grounds about an establishment must be maintained to prevent conditions that could lead to contamination or adulteration of product or that could prevent FSIS program employees from performing assigned tasks." The commenters contended that the phrase "grounds about an establishment" is inconsistent with recent FSIS policy that establishment management is responsible for defining the boundaries of their facilities. Specifically, commenters cite recent FSIS Directive 7640.1, "Inspection Duties Related to Facilities and Equipment, and Plant Operated Quality Control Programs," which states that inspection program employees are to request from establishment management written designation of the official premises' boundaries. Therefore, these commenters have suggested that "grounds about an establishment" be revised to read "grounds as designated by the establishment."

*Response:* FSIS disagrees. The Agency sees no inconsistency between the directive and the performance standard as proposed. Proper maintenance of the

grounds about an establishment is essential for ensuring good sanitation. FSIS inspection program employees request written designation of establishment boundaries only to facilitate their inspection of the establishment. Establishments are responsible for preventing adulteration of product even if the sources are outside the designated boundaries of the establishment. Revising the performance standard to address only areas within the designated boundaries could mislead establishments into believing that they are not responsible for preventing such adulteration, especially when it originates from areas outside of the designated boundaries of the processing operations, but under the control of the establishment. Accordingly, FSIS is not making any changes to the rule language as proposed.

*Comment:* FSIS proposed to require that establishments "have in place an integrated pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities." One commenter suggested that FSIS delete the word "integrated," arguing that it is confusing and unnecessary.

*Response:* Integrated pest management (IPM) is a widely recognized system of agricultural pest control that takes into account pest ecology and the effect of pesticides and other pest control chemicals on the environment and on food. For the most part, IPM has been used within agricultural production systems. However, IPM also is applicable to meat and poultry processing.

FSIS has rethought its tentative view that meat and poultry establishments should implement IPM systems. Although FSIS encourages establishments to develop or adopt IPM, FSIS has concluded that IPM is not absolutely necessary to ensure the production of unadulterated meat or poultry products. In this final rule, FSIS is requiring that any pest control system used by an establishment be designed and implemented so as to ensure that product is not adulterated either by pests or by the products designed to control them and, further, that the pest control system does not create insanitary conditions.

*Comment:* The remaining comments on pest control addressed the proposal to eliminate the requirements that pesticides and rodenticides be approved by FSIS prior to their use in official establishments. Several commenters argued that without prior approval of pesticides and prescriptive requirements concerning their use,

establishments will adulterate product or create insanitary conditions that could lead to adulteration.

*Response:* FSIS' review and approval of pesticides and rodenticides prior to their intended use provided some assurance to meat and poultry processors that proper use of these compounds would not result in the adulteration or contamination of food products. However, FSIS has concluded after careful consideration of the issue that this prior approval program is unnecessary and inconsistent with HACCP. Under the HACCP regulations, establishments are responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products. Consequently, establishments are responsible for ensuring that the pesticides and rodenticides they use are safe and effective.

Further, FSIS prior approval of pesticides and rodenticides has been somewhat redundant with the Environmental Protection Agency (EPA) requirements and review programs for these compounds. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA reviews pesticide formulation, intended use, and other information; registers all pesticides for use in the United States; and prescribes labeling, use, and other regulatory requirements to prevent unreasonable adverse effects on the environment, including humans, wildlife, plants, and property. Any meat or poultry establishment using a pesticide must follow the FIFRA requirements.

FSIS is requiring that documentation substantiating the safety of pesticides and rodenticides be available to FSIS inspection program employees for review (§ 416.4(c)). The documentation will need to include proof of EPA registration and could also include other any information, such as letters of guaranty from the manufacturer, labels, application instructions, and records of use that establish the safe and effective use of these products. FSIS inspection program employees will review these records as necessary, as well as observe the application and storage of pesticides and rodenticides to ensure the maintenance of sanitary conditions and that product is not adulterated. (For further discussion of prior approval of pesticides and other chemicals, see the section "Cleaning Compounds and Sanitizers" below.)

#### *Establishment Construction: Proposed § 416.2(b)*

*Comment:* Several commenters objected to the language of the proposed

provision: "Establishment buildings, including their structures, rooms, and compartments must be of sound construction, kept in good repair, and be of sufficient size to allow for the sanitary processing, handling, and storage of product." Commenters argued that the requirement regarding "sufficient size" constitutes a new standard for sanitation. Commenters also argued that the phrase "sanitary processing, handling, and storage of product" is too general; they suggested that the construction standard be based upon preventing adulteration of product.

*Response:* FSIS disagrees that the requirement that rooms in an official establishment be of "sufficient size" constitutes a new standard. Although the previous regulations did not explicitly require rooms to be any particular size, the requirement that rooms be of sufficient size to prevent the adulteration of product was implicit. Moreover, this requirement is fully consistent with the FMIA and PPIA. An establishment would very likely be in violation of the statutory and regulatory prohibitions against product adulteration if its processing or storage rooms were so small that adequate separation of raw and ready-to-eat product were impossible. FSIS is merely making this requirement explicit in this performance standard.

FSIS agrees that the proposed language regarding "sanitary processing, handling, and storage of product" should be revised to make clear the obligation specified in this regulation. For clarity and consistency with the other performance standards, FSIS is revising this performance standard to read: "Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions."

*Comment:* A few commenters stated that while large establishments might be able to innovate effectively under the proposed performance standards for construction, many small establishments lack the expertise to innovate in facility construction and design and need to follow specific requirements in order to maintain sanitary operations that produce safe meat and poultry products.

*Response:* FSIS disagrees. The design or alteration of facility construction or layout is well within the capability of most, if not all, meat and poultry establishments, regardless of size.

Moreover, in this rule, FSIS is not requiring establishments to innovate in regard to facility construction or layout. Establishments currently maintaining sanitary conditions will not need to make any changes to their construction or layout as a result of this performance standard. Further, FSIS is making available a compliance guide for the sanitation performance standards, including the standards for construction. Establishments remodeling or undertaking new construction may consult this guide or the various national building and construction codes, State and local laws and codes, and other relevant resources available from trade associations, consultants, and nonprofit organizations.

*Comment:* One commenter questioned FSIS' recommendation that establishments consult the Food Code, as well as national building and construction codes, when designing or building facilities. The commenter maintained that because these documents have no force of law, establishments do not have to follow their guidance, and further, that these documents are not always applicable to the unique requirements of meat and poultry processing establishments. This commenter concluded that specific design and construction requirements are necessary to ensure that meat and poultry establishments are built properly.

*Response:* FSIS does not agree that specific requirements for establishment design and construction are necessary to ensure that meat and poultry are not adulterated. FSIS is adopting performance standards for construction that provide establishments, regardless of size, the flexibility to design facilities and equipment in the manner they deem best to maintain the required sanitary environment for food production. Further, as stated above, if establishments are maintaining sanitary conditions, there is no reason to believe that they will not be in compliance with the new performance standards for design and construction, as long as their facilities are maintained in good repair. Also, as stated above, they may follow the recommendations in the Food Code or the national building and construction codes, many of which have been adopted as requirements by State and local governments. If establishments do so, they should be in compliance with the standards.

*Comment:* One commenter requested that FSIS delete the examples of vermin given in proposed § 416.2(b)(3): "Walls, floors, ceilings, doors, windows, and other outside openings must be

constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice." The commenter argued that these examples are unnecessary.

*Response:* These examples are illustrative of the types of vermin known to commonly infest meat and poultry establishments and, therefore, FSIS is retaining them in the regulations.

*Comment:* Finally, although no commenter specifically addressed the proposed standard concerning the separation of edible and inedible product, FSIS believes that the proposed standard could be misunderstood and is making a revision to clarify its intent. FSIS proposed to require that "Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored." FSIS did not intend to imply that rooms where edible product is processed, handled, or stored could never be used for the processing, handling or storage of inedible product. FSIS has allowed, and will continue to allow, establishments to process, handle, or store edible and inedible product in the same room as long as they are separated by time or space, in a manner sufficient to prevent the adulteration of the edible product or the creation of insanitary conditions.

*Response:* FSIS is adopting a revised standard that states: "Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions."

#### *Light: Proposed § 416.2(c)*

*Comment:* A few commenters opposed the proposed performance standard that establishments provide "Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated \* \* \*". These commenters maintained that by allowing establishments to determine whether light quality and intensity is sufficient, FSIS, in fact, would be allowing establishments to provide lighting that is not sufficient to ensure sanitation. One commenter doubted that establishments would follow the recommendations for lighting contained in the Food Code, as suggested by FSIS. Another commenter recommended that FSIS maintain the existing 30-foot candle requirement for light intensity at poultry working surfaces and extend the

same requirement to meat establishments.

*Response:* FSIS disagrees. FSIS does not believe it is necessary to prescribe specific light intensities to ensure sanitation in meat and poultry processing areas because establishments must determine what light intensities are appropriate to ensure sanitation in different operational contexts. Importantly, however, as with all of the sanitation performance standards, FSIS will continue to verify through inspection that the lighting meets the performance standard.

The previous requirements for lighting in poultry establishments in § 381.52 prescribed specific light intensities for different areas of the establishment. For example, FSIS required that all rooms in which poultry was killed, eviscerated, or otherwise processed have 30-foot candles of light intensity on all working surfaces. The comparable regulations for red meat establishments in § 308.3(b) did not contain such specific requirements, but required only that meat establishments have "abundant light, of good quality and well distributed." However, the intent of these requirements was the same for both meat and poultry establishments: there must be enough light of adequate quality to monitor sanitary conditions and processing operations and to examine product for evidence of adulteration. New § 416.2(c) establishes this intent as a single performance standard applicable to both meat and poultry establishments, which is wholly consistent with the purpose of the current regulations.

It also is important to note that FSIS is not rescinding the specific light intensity requirements for inspection program employee and reprocessing stations set out in §§ 307.2 and 381.36. FSIS has determined that these specific requirements are still necessary to ensure appropriate conditions for effective inspection.

#### *Ventilation: Proposed § 416.2(d)*

*Comment:* FSIS proposed that meat and poultry establishments provide "ventilation adequate to eliminate odors, vapors, and condensation." Several commenters maintained that it would be impossible for establishments to "eliminate" odors, vapors, and condensation. They suggested that the standard be revised to require that ventilation be adequate to control odors, vapors, and condensation to the extent necessary to prevent the adulteration of product.

*Response:* FSIS agrees and has revised the standard to require that ventilation be adequate to control odors, vapors,

and condensation to the extent necessary to prevent adulteration of product and to prevent the creation of insanitary conditions which can lead to product adulteration.

*Plumbing and Sewage Disposal:  
Proposed §§ 416.2(e) and (f)*

*Comment:* In the preamble to the proposed rule, FSIS recommended that establishments consult the National Plumbing code when designing or building a plumbing system and stated that "a plumbing system in compliance with the National Plumbing Code in most instances would meet the proposed performance standards for plumbing." One commenter supported the use of the National Plumbing Code by establishments but questioned whether there were certain provisions in the Code that FSIS has determined would be inadequate to meet the performance standard.

*Response:* FSIS has not determined that any of the provisions of the National Plumbing Code are inappropriate or inadequate as models for plumbing systems in meat and poultry establishments. However, compliance with the National Plumbing Code or any other code does not necessarily establish compliance with FSIS regulations. For instance, it could be possible to build a plumbing system that meets the standards of the National Plumbing Code but also creates insanitary conditions that could cause the adulteration of product. FSIS continues to recommend that meat and poultry establishments consult the National Plumbing Code when designing or building a plumbing system, but also encourages establishments to keep in mind the relevant requirements of FSIS, other Federal Agencies, and State and local governments.

*Comment:* A few commenters opposed the removal of requirements that features of plumbing and sewage systems, such as traps and vents, be prior-approved by FSIS program employees for safety and efficacy.

*Response:* As the Agency has stated throughout this document, FSIS fundamentally disagrees with those commenters who oppose the elimination of prior approval requirements. It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water for processing and other purposes and move waste and sewage from the establishment without adulterating product or creating insanitary conditions. There are many ways to achieve these goals that are consistent

with FSIS regulations, State and local laws, and the Food Code. Required prior approval of these systems undercuts this objective and would deprive establishments of the flexibility to innovate and create sound, effective plumbing and sewage systems that ensure sanitary operating conditions. FSIS will continue to verify, through inspection, that plumbing and sewage systems neither adulterate product nor create insanitary conditions.

*Water Supply and Reuse: Proposed  
§ 416.2(g)*

*Comment:* One commenter believed that FSIS suggested in the preamble to the proposal that compliance with the EPA standard for water potability might not be sufficient to ensure that water used by meat and poultry establishments is potable.

*Response:* FSIS proposed a water supply performance standard intended to make transparent the current requirement that potable water comply with EPA's National Primary Drinking Water regulations. These regulations are promulgated under section 1412 of the Public Health Service Act, as amended by the Safe Drinking Water Act, and are applicable to public water systems. The EPA standard of water potability is sufficient and FSIS is adopting the performance standard as proposed.

*Comment:* Another commenter questioned the proposed requirement that establishments make available to FSIS any water reports "issued under the authority of the State health agency, certifying or attesting to the quality of the water supply." The commenter argued that this requirement would be ineffective as an indicator of water potability unless FSIS specified the frequency at which an establishment must have its water supply tested.

*Response:* The EPA National Primary Drinking Water regulations, contained in 40 CFR part 141, require testing of drinking water for fecal coliforms and other contaminants at specified frequencies. Because FSIS is requiring that water used by meat and poultry establishments meet the EPA requirements, which include testing requirements, FSIS does not need to promulgate separate testing requirements. Certifications of water potability provided by State or local governments or other responsible entities will show whether water meets the EPA requirements.

Some meat and poultry establishments use private wells for their water supply. EPA classifies private wells as "noncommunity" water sources and does not require testing for potability. It also is unlikely that State

or local governments would test such wells for potability. If an establishment uses a private well, FSIS is requiring that the establishment make available to FSIS documentation, renewed at least semi-annually, certifying the potability of its private well water. Most establishments will obtain this documentation from private laboratories.

FSIS is finalizing this requirement concerning the potability of well water in response to the above comment. Although the Agency did not specifically propose this approach, it is consistent with the proposal, which focused on how to ensure the potability of water used in all establishments. Moreover, it is not a new requirement. It is the codification of a policy that FSIS has been enforcing under FSIS Directive 11,000.1, the "Sanitation Handbook for Meat and Poultry Inspection." This Directive was rescinded by FSIS Notice 3-98 on January 16, 1998. Another FSIS document concerning this policy, entitled "Approved Water Systems," will be rescinded upon the effective date of this rule.

*Comment:* Several commenters objected to the proposed performance standards for water reuse because, they argued, the proposed standards would allow establishments to wash raw product, equipment, and utensils with non-potable water, and the possibility of product adulteration would therefore be greatly increased. One commenter suggested that FSIS require water to be "heat pasteurized" before reuse on raw or ready-to-eat product.

*Response:* In many circumstances, establishments can reuse water in a manner that will neither adulterate product nor create insanitary conditions. FSIS already permits certain uses of nonpotable water. For example, water is recirculated in tanks to chill raw poultry; water treated by an advanced wastewater treatment system can be used to wash equipment or raw product, if followed by a potable water rinse; and nonpotable, reuse water can be used to wash floors or equipment in areas where edible product is not handled. FSIS is making final performance standards that will provide for the reuse of water in numerous processing contexts, provided that the establishment takes actions necessary to ensure that product is not adulterated by the water and that sanitation is not compromised. Establishments are required to document and monitor water reuse activities either in their Sanitation SOP's or HACCP plans.

*Comment:* One commenter expressed concern about the proposed requirement

that water used or reused to chill or cook ready-to-eat product be free of pathogens. This commenter and others stated that the stated goal of the performance standards for water, processing solution, and ice reuse should be to prevent meat and poultry products from becoming adulterated by pathogens, rather than preventing water, ice, or solutions from being contaminated with pathogens, fecal coliforms, and other hazardous substances. These commenters maintained that establishments will control pathogens in the processing environment, in this case water, through HACCP and Sanitation SOP's and recommended that the performance standards for water, ice, and solutions reuse be revised accordingly.

*Response:* FSIS does not agree with the commenters' suggestion. In many cases, the presence of fecal coliforms, pathogens, or other contaminants in reuse water, ice, or processing solutions indicates insanitation that may, in fact, lead to the adulteration of meat and poultry products. The control of pathogens in water used in processing, therefore, is essential for ensuring that meat and poultry products do not become adulterated. The performance standards establish the necessary conditions to ensure that water, ice, and solution reuse do not compromise sanitation or cause the adulteration of product. Establishment Sanitation SOP's and HACCP plans must provide for compliance with these sanitation standards.

#### *Ice and Solution Reuse: Proposed § 416.2(h)*

*Comment:* Several commenters maintained that the hazards inherent in ice and solution reuse were identical to those in water reuse and suggested, therefore, that the performance standards be combined for consistency.

*Response:* FSIS agrees and has made final a single set of reuse performance standards applicable to water, ice, and solutions. However, because of the different physical characteristics and uses of water, ice, and solutions, it is expected that establishments will meet the performance standards for these substances in different ways. For example, an establishment recirculating water in a chill tank for raw poultry might add chlorine to the water to reduce the number of pathogens. An establishment reusing ice to chill raw poultry might bag the ice to prevent it from contacting product.

#### *Dressing Rooms, Lavatories, and Toilets: Proposed § 416.2(i)*

*Comment:* Numerous commenters opposed the proposed performance standard concerning the number of lavatories and toilet facilities in official establishments:

Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled. Where both sexes are employed, separate facilities must be provided.

These commenters claimed that many establishments have crowded, insanitary conditions now, and, if given this performance standard instead of a more prescriptive requirement, establishments would not provide a sufficient number of lavatories and toilet facilities. One commenter, however, argued that the standard is, in fact, too prescriptive in that it requires separate facilities for both sexes. This commenter stated that Federal, State, and local labor laws already provide for this.

*Response:* As the Agency has stated throughout this document, it is prudent and reasonable to replace prescriptive sanitation requirements with performance standards that articulate the objectives or results that establishments must achieve. Thus, FSIS is replacing the prescriptive requirements concerning establishment lavatories, toilet facilities, and their sanitation with a performance standard. Furthermore, other Federal law already does govern lavatories and toilet facilities in places of employment.

The Occupational Safety and Health Administration (OSHA) of the Department of Labor has promulgated regulations concerning toilet facilities in the workplace in 29 CFR 1910.141, "Sanitation." Paragraph (c)(1)(i) of this regulation sets forth requirements for the number of toilet facilities in all permanent places of employment. Official meat and poultry establishments are governed by these requirements. Thus, FSIS has determined that it is not necessary to add a more specific provision regarding the number of toilets to the performance standard it proposed.

In regard to the issue of requiring separate toilet facilities for men and women, OSHA also has set forth requirements, again in 29 CFR 1910.141(c)(1)(i): "toilet facilities, in toilet rooms separate for each sex, shall be provided in all places of

employment," and, further, "Where toilet rooms will be occupied by no more than one person at a time, can be locked from the inside, and contain at least one water closet, separate toilet rooms for each sex need not be provided." For consistency with this OSHA requirement, FSIS has removed the proposed provision requiring separate lavatories and toilet facilities.

#### *Equipment and Utensils: Proposed § 416.3*

*Comment:* Numerous commenters objected to the proposed elimination of the requirement in §§ 308.3(d)(4) and 308.8 that utensils and equipment used to dress diseased meat carcasses be cleaned with either 180 °F water or an approved disinfectant. Several commenters contended that the use of 180 °F water has been the method "proven" to be effective for sanitizing implements. These commenters submitted no supporting data, however. A few commenters recommended that FSIS require a minimum water temperature of at least 155 °F to 160 °F, as water in this temperature range is purported to kill *E. coli* O157:H7. Several commenters questioned the studies cited by FSIS as support for rescinding the 180 °F requirement. These commenters recommended that FSIS commission or conduct a new study to determine the water temperature that is most effective for controlling bacteria in a slaughter environment. Finally, one commenter argued that by rescinding the 180 °F water requirement, FSIS is contradicting its other policy of "promoting" the use of steam cabinets as a processing step to kill bacteria.

*Response:* For HACCP systems to be effective, meat and poultry establishments must be afforded the flexibility to take whatever actions are necessary to produce safe products. Meat establishments must determine what is necessary, in the particular context of their processing environment, to clean implements used to dress diseased carcasses so that those implements will not adulterate product. Under the performance standard, many meat establishments are likely to continue using 180 °F water for this purpose, but others will use different means that they will have determined are more suitable and as effective.

The studies summarized by FSIS in the proposal raise significant questions about the efficacy of 180 °F water for the cleaning of implements used to dress diseased carcasses. FSIS cited these studies to emphasize that this prescribed treatment may not be effective in every processing



environment and, therefore, that a performance standard would be more appropriate for ensuring that meat establishments maintain proper sanitation within their operations. FSIS is not planning to conduct or sponsor any additional studies at this time, but certainly will evaluate any research developments in this area.

Finally, FSIS has endorsed the use of steam pasteurization as an antimicrobial treatment for the surfaces of meat carcasses. FSIS has not prescribed, however, a specific temperature for the steam or a specific method for its application. Similarly, FSIS will no longer require a specific method for the cleaning of implements used to dress diseased carcasses.

*Comment:* Several commenters opposed the proposed performance standard regarding equipment and FSIS inspection program employees: "Equipment and utensils must not interfere with inspection procedures or interfere with inspection by FSIS inspection personnel." These commenters argued that this standard is unnecessary because the general requirement that establishments not interfere with FSIS inspection is implicit in all of the regulations.

*Response:* The FMIA, PPIA, and the regulations specifically prohibit the forcible interference with FSIS program employees performing inspection or any other duties prescribed by the FMIA, PPIA, or the regulations. Moreover, the requirement that establishments not interfere with FSIS inspection is implicit throughout FSIS regulations. However, it is important to establish a performance standard regarding the inspection of the sanitary condition of equipment. Equipment in an official establishment must not be constructed or operated in a manner that would prevent FSIS inspection program employees from determining whether the equipment is in sanitary condition. If meat or poultry processing equipment is built, located, or operated in a manner that prevents it from being inspected to determine whether it has been cleaned or sanitized so as to ensure that it will not be the cause of product adulteration, FSIS may withhold the mark of inspection from product processed using that equipment. FSIS has revised the proposed performance standard, as follows, to clarify this intent: "Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting equipment or utensils to determine whether they are in sanitary condition."

#### *Food Contact Surface Cleaning and Sanitation: Proposed § 416.4(a)*

*Comment:* Numerous commenters objected to the proposed requirement that "all food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned daily prior to starting operations \* \* \*." Commenters stated that many establishments currently operate successfully for extended periods (more than 24 hours), cleaning and sanitizing as necessary. Also, several commenters noted that certain types of equipment, such as blast freezers and high temperature ovens, can be operated over extended periods without posing a significant food safety risk. Finally, a few commenters suggested that an establishment's Sanitation SOP or HACCP plan should dictate frequency of cleaning food contact surfaces.

*Response:* FSIS agrees that it is possible for an official establishment to safely operate for an extended period (more than 24 hours) without re-sanitizing all food contact surfaces. It is also true that more frequent sanitizing may be necessary. Accordingly, FSIS is finalizing a performance standard for operational sanitation requiring that "All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product." The regulation, as revised, is consistent with the Sanitation SOP and HACCP requirements. Establishments must comply with the Sanitation SOP requirements regarding food contact surfaces in § 416.12(c): "Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils."

#### *Non-Food Contact Surface Cleaning and Sanitation: Proposed § 416.4(b)*

*Comment:* Several commenters stated that the language proposed for the performance standard for non-food contact surfaces was unnecessarily prescriptive and inconsistent with the other performance standards because it required that such surfaces be cleaned "as necessary to prevent the physical, chemical, or biological contamination or adulteration of product," rather than simply to prevent adulteration of product.

*Response:* FSIS agrees and has revised the standard to be consistent with the revised standard in § 416.4(a): "Non-

food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product." Obviously, during the normal course of an establishment's operations, meat and poultry products should not come in contact with "non-food contact surfaces." Therefore, as long as such contact did not occur, it would be unlikely that these surfaces would ever directly adulterate product. However, if non-food contact surfaces are insufficiently cleaned or sanitized, insanitary conditions within the establishment can result, potentially leading to product adulteration. FSIS has revised this performance standard by deleting the specific reference to "physical, chemical, or biological contamination" and by requiring that non-food contact surfaces be cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product.

*Comment:* One commenter claimed that non-food contact surfaces in establishments, such as floors, drains, and walls, are highly contaminated. This commenter suggested that FSIS revise the performance standard to require daily cleaning and sanitizing of non-food contact surfaces.

*Response:* In many establishments, daily cleaning and sanitizing of non-food contact surfaces may not be necessary for the maintenance of sanitary conditions or the prevention of product adulteration. FSIS will not, therefore, mandate specific time intervals for this requirement. If the conditions in an establishment are such that floors, drains, walls, and other non-food contact surfaces are highly contaminated on a regular basis, the establishment may need to provide for the appropriate frequency of cleaning and sanitizing of those surfaces in either its HACCP plan or Sanitation SOP's. FSIS is confident that insanitary conditions of non-food contact surfaces in official establishments will be detected by FSIS inspection program employees during verification of an establishment's HACCP plans and written Sanitation SOP's.

#### *Cleaning Compounds and Sanitizers: Proposed § 416.4(c)*

FSIS proposed to eliminate the regulatory requirements mandating that certain nonfood compounds and proprietary substances be approved by the Agency prior to their use. Specifically, FSIS proposed to rescind the following regulations:



§ 308.3(h)—requirements that FSIS approve pesticides, rodenticides, and insecticides prior to use in certain areas of meat establishments;

§ 308.8(c)—requirements that FSIS approve, prior to use, disinfectants used to clean implements that have contacted diseased meat carcasses; and

§ 381.60—requirements that germicides, insecticides, rodenticides, detergents, wetting agents, and similar compounds be approved by FSIS prior to use in poultry establishments.

FSIS did not propose to discontinue its policy of approving other proprietary substances or nonfood compounds prior to their use in official establishments. As a matter of policy, FSIS has reviewed and approved, prior to use, most other nonfood compounds and proprietary substances, including: branding and tattoo inks; poultry and hog scald agents; rendering agents; certain cleaning compounds; paint removers; antimicrobial agents; hand washing and sanitizing agents; water treatments; solvent cleaners; sewer and drain cleaners; and lubricants. Following its review, FSIS has listed all approved nonfood compounds and proprietary substances in Miscellaneous Publication Number 1419, *List of Proprietary Substances and Nonfood Compounds*.

Shortly after FSIS published the proposal to revise the sanitation regulations, FSIS mistakenly released information that mischaracterized the proposal's provisions concerning the prior approval of nonfood compounds and proprietary substances. On September 11, 1997, the FSIS Compound and Packaging Review Branch mailed a notice to chemical manufacturers and other businesses announcing a change of address. Included with that notice was a facsimile of the first page of a proposed rule, incorrectly identified as the sanitation proposal, FSIS Docket No. 96-037P, announcing that the Agency was discontinuing its policy of approving *all* nonfood compounds and proprietary substances prior to their use in official meat and poultry establishments.

In order to clear up any confusion regarding the matter, FSIS published a notice in the **Federal Register** (FSIS Docket No. 97-062N; 62 FR 55995) explaining the situation and correcting the erroneous information. Further, in order to ensure that the public had ample opportunity to submit comments on the sanitation proposal and its provisions concerning nonfood compounds and proprietary substances, FSIS reopened the comment period for that proposal for 15 days, from October

28, 1997, to November 10, 1997 (FSIS Docket 96-037R; 62 FR 55997).

On February 13, 1998, FSIS announced in a notice (FSIS Docket No. 97-007N; 63 FR 7319) that it did, in fact, intend to discontinue approving all nonfood compounds and proprietary substances prior to their use in official meat and poultry products establishments. FSIS emphasized that it would continue to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary additives and nonfood compounds. Further, FSIS also explained its plan to maintain a small staff with expertise in nonfood compounds and proprietary substances. This staff will keep abreast of developments in chemical manufacturing and use, maintain liaison with outside organizations that have an interest in this matter, and issue technical guidance, particularly to small meat and poultry plants, as circumstances warrant. Finally, FSIS requested comment on possible alternatives to the FSIS prior approval program, including the option of third party review and approval of nonfood compounds and proprietary substances.

The comments FSIS received on this issue, whether in response to the sanitation proposal, the letter distributed by the Compounds and Packaging Review Branch, or the February 13 notice, do not differ substantively. While a few commenters supported the proposed regulatory and policy changes, most of the comments were submitted by chemical manufacturers, and most were in opposition to ending the prior approval program for all nonfood compounds and proprietary substances. In response to the letter, FSIS received 68 comments. Because these commenters believed that they were responding to an FSIS proposed rulemaking, FSIS maintained their comments on file in the FSIS Docket Room. In response to the February 13 notice, FSIS received 35 comments. Below, FSIS responds to all of the issues raised in all of the comments concerning the FSIS plan to eliminate the prior approval program.

**Comment:** The majority of commenters opposed to ending the prior approval program argued that without prior approval, unscrupulous chemical manufacturers will market unsuitable and possibly dangerous chemicals to meat and poultry establishments and that the use of such chemicals would inevitably lead to the adulteration of product. Further, they argued that it would be difficult for FSIS inspection program employees to prevent such adulteration since they would not be

able to consult the *List of Proprietary Substances and Nonfood Compounds*. Several commenters contended that without the *List of Proprietary Substances and Nonfood Compounds*, FSIS inspection program employees will make inconsistent or arbitrary decisions in regard to what compounds establishments may use.

**Response:** FSIS disagrees. The FMIA and PPIA require that meat and poultry products be neither adulterated nor misbranded through the use of proprietary substances and nonfood compounds. Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately. In light of these requirements, FSIS anticipates that establishments considering purchasing and using nonfood compounds or proprietary substances will demand formulation or other information from chemical manufacturers before making purchase decisions. Manufacturers who fail to provide such information could lose their market share.

FSIS inspection program employees will continue to verify that proprietary substances and nonfood compounds do not adulterate meat and poultry products. Enforcement activities in this regard will include, but will not be limited to, direct observation of establishment operations and inspection of an establishment's premises and product, as well as sampling of product for chemical residues, as necessary, and review of establishment records. Establishments will document the use of proprietary substances and nonfood compounds in a variety of records, depending on the nature of the compound and its use. FSIS inspection program employees will review Sanitation SOP's, HACCP plans, use directions, pest control certifications, letters of guarantee, and other materials furnished to establishments by chemical manufacturers and suppliers.

In response to comments, FSIS is finalizing an additional regulatory requirement in regard to the use of nonfood compounds and proprietary substances in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since, as stated above, documentation substantiating the safety of a chemical varies with the nature and intended uses of that chemical. For example, for a pesticide, an

establishment should have documentation showing that the compound is registered with EPA and the label information for the pesticide. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration (FDA) regulations in 21 CFR 178.1010. For an antislip agent, an establishment may satisfy the regulations with a letter of guarantee and use instructions from the manufacturer certifying that if used in accordance with directions, the compound will neither adulterate product nor create insanitary conditions. This documentation requirement not only will assist FSIS inspection program employees in determining whether the use of given compound is proper and safe, but also will ensure that meat and poultry establishments have adequately reviewed and evaluated the chemicals used in their food processing environments.

FSIS inspection program employees may, of course, disallow a specific use of a chemical in an official establishment if documentation is not available or is inadequate, if the establishment misuses the nonfood compound or proprietary substance, or if there is reason to believe a specific use will lead to insanitation or product adulteration. FSIS program employees will be instructed to direct any questions or concerns regarding the use of nonfood compounds and proprietary substances to the FSIS Technical Services Center. Further, FSIS is publishing a new Directive to assist inspection program employees in verifying the safety of the use of nonfood compounds and proprietary substances in official meat and poultry establishments.

*Comment:* Some commenters maintained that small establishments lack the resources and technical expertise to determine whether chemical compounds are safe and effective and, therefore, would be adversely affected by the elimination of FSIS review and approval. Several of these commenters urged FSIS to provide guidance material to industry concerning the appropriate formulation and use of nonfood compounds and proprietary substances.

*Response:* FSIS does not anticipate that the elimination of its prior approval program will substantially affect small meat and poultry establishments. These establishments are or should be already aware of which chemicals have been approved by FSIS. Moreover, competition will compel chemical

manufacturers to provide meat and poultry establishments of all sizes with data that establish that their compounds are safe and effective. Likewise, FSIS is making available guidelines for compliance with the sanitation performance standards that explicitly address the appropriate formulation and safe use of nonfood compounds and proprietary substances. The guidelines are based upon the FSIS's regulatory experience, the requirements of other Federal agencies, and the criteria previously used by FSIS for reviewing and approving nonfood compounds and proprietary substances. Establishments should refer to those guidelines. Furthermore, although the guidelines are directed primarily to regulated meat and poultry establishments, chemical manufacturers may find them useful in developing and marketing their products.

*Comment:* A few commenters, including several non-government standard-setting organizations, strongly supported third-party review and certification of nonfood compounds and proprietary substances.

*Response:* FSIS encourages third-party standards organizations and independent laboratories to develop systems for testing and certifying nonfood compounds and proprietary substances. Such certification would encourage the development and marketing of effective, safe, and innovative products. Chemical manufacturers whose products meet FSIS performance standards and other agency requirements will have ample incentive to publicize the fact that their products are approved by third party organizations or independent laboratories. It is not likely that FSIS will officially sanction any particular organization's certification as definitive evidence of compliance with FSIS requirements. However, FSIS would obviously give careful consideration to valid third-party certifications when questions arise regarding the safety of a nonfood compound or proprietary substance.

*Comment:* Several commenters noted that some of the nonfood compounds and proprietary substances previously approved by FSIS, including general cleaners, hand soaps, sewer and drain cleaners, and certain water treatments, are not, in fact, reviewed or approved by other Federal agencies. These commenters contended that, consequently, continued review and approval of these compounds by FSIS is necessary. In one comment, FDA raised specific concerns regarding the proposed discontinuation of prior approval for hand cleaners and

sanitizers. Although some hand treatments are considered over-the-counter drug products and therefore regulated by FDA, others are not.

*Response:* FSIS does not agree that prior approval of these chemicals is necessary to ensure the safety of meat and poultry products. Meat and poultry establishments have the responsibility of ensuring that the nonfood compounds and proprietary substances that they use will not adulterate product or create insanitary conditions. As stated above, FSIS will verify that these chemicals are being used appropriately through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. FSIS anticipates that competition will compel chemical manufacturers to demonstrate to meat and poultry establishments that their products are safe and satisfy the standards established in these regulations.

Specifically in regard to the use of hand treatments and sanitizers, FSIS prior approval is unnecessary. Hand care products formulated with chlorhexidine gluconate and intended to be used as an antimicrobial hand cleaner or hand sanitizer/dip in food handling and processing, as well as hand care treatments intended for use as a "barrier" or "shield" to prevent or mitigate human disease by protecting skin from exposure to toxic chemicals or pathogenic microorganisms, are considered "drugs" and possibly "new drugs" under the Federal Food, Drug, and Cosmetic Act (FFDCA). Consequently, FDA regulates and registers these hand treatments. Establishments using such chemicals should keep registrations on file for review by FSIS inspection program employees.

Other hand treatments, however, are not currently regulated or registered by FDA. It is the responsibility of establishments to ensure that such treatments do not adulterate product or create insanitary conditions. As with other chemicals, FSIS will verify that hand treatments are being used appropriately through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. FSIS is publishing guidance on the appropriate use of hand treatments in the sanitation performance standards compliance guide. FSIS also is continuing to consult with FDA regarding the appropriate use of hand treatments, and will modify the compliance guide in the event of changes in FDA policies.

*Comment:* One trade association cited concerns regarding labeling and

marketing claims for nonfood compounds and proprietary substances previously approved and listed by FSIS. This commenter requested that FSIS explicitly allow manufacturers of previously approved chemicals to market them as such.

*Response:* FSIS will neither approve nor disapprove marketing claims or labeling for the nonfood compounds and proprietary substances used in establishments. Chemical manufacturers may market or label their products as being previously approved by FSIS, as long as their claims are truthful and not misleading, as is required by applicable law. Meat and poultry establishments should keep in mind that since FSIS is discontinuing its prior approval program for these products, previous approval of a product by FSIS does not necessarily mean that it is safer or more effective than a new product that has not been reviewed and approved.

Documentation required to be available under the regulation may cite that products were previously approved by FSIS for a particular use and that the formulation of that product has not changed. This information may facilitate decisions by FSIS program employees when reviewing documentation that substantiates the safety of a nonfood compound or proprietary substance.

*Comment:* A few commenters argued that in regard to the proposed elimination of its prior approval program, FSIS must perform environmental impact analyses pursuant to the requirements of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) and the Council for Environmental Quality regulations in 40 CFR parts 1500–1508. These commenters noted that FSIS has been granted a categorical exclusion from NEPA requirements by USDA regulation (7 CFR 1b.4), unless “the agency head determines that an action may have a significant environmental effect.” They concluded that the elimination of prior approval for nonfood compounds and proprietary substances in general, and specifically for pesticides, could have a significant, adverse impact on human health and the environment and therefore that FSIS should conduct an environmental assessment or impact analysis as required by NEPA. Two commenters also claimed that FSIS’s planned elimination of its prior approval program is inconsistent with the intent of E.O. 13045, which encourages Federal agencies to “identify and assess environmental health risks and safety risks that may disproportionately affect children” and result from regulatory action.

*Response:* The Administrator of FSIS has determined that the elimination of prior approval of nonfood compounds and proprietary substances will not have an adverse impact on the environment or human health, and therefore, that it is not necessary for FSIS to perform an environmental impact assessment for this action. As stated above, FSIS is continuing to require that meat and poultry products be neither adulterated nor misbranded through the use of proprietary substances and nonfood compounds and that the use of these substances and compounds must not create insanitary conditions. FSIS inspection program employees will verify that these chemicals are being used appropriately and are not adulterating product through inspection, review of documentation substantiating the safety of the chemicals, and if necessary, sampling and testing. Other Federal and state requirements concerning the use, storage, or disposal of these chemicals will not be affected by this rule. There is no reason to believe, therefore, that the discontinuation of the FSIS prior approval program for nonfood compounds and proprietary substances will allow meat and poultry establishments to use these chemicals in any manner that would have an adverse impact on human health and the environment.

Finally, because FSIS has determined that this action will not have any significant impact on the environment or on human health, FSIS has similarly determined that this action will not have a disproportionately adverse impact on the health of children and is, therefore, consistent with the intent of E.O. 13045.

#### *Denaturants*

During the course of reviewing the comments, FSIS discovered that it had not proposed to rescind in §§ 314.3 and 381.95, which require establishments to use only prior approved denaturants for condemned meat and poultry, even though FSIS has listed approved denaturants in the *List of Proprietary Substances and Nonfood Compounds*. Denaturants are chemicals used to color or affect condemned meat and poultry products in a manner that readily identifies them as inedible to establishment employees and FSIS inspection program employees, so that the product will not be processed, shipped, or marketed as edible product. In the near future, FSIS will publish a proposal to rescind these prior approval requirements for denaturants and replace them with a performance standard. The standard that FSIS

intends to propose will take into account FDA policy regarding denaturants applied to condemned meat and poultry products used for animal feed. Until the FSIS proposal is published and made final, the requirements regarding prior approval of denaturants will remain in effect.

#### *Operational Sanitation: Proposed 416.4(d)*

*Comment:* Several commenters opposed the proposal to replace with a performance standard § 381.47(e), which required that rooms where mechanical equipment is operated for the deboning of raw poultry be maintained at 50 °F or less. FSIS considered this requirement to be overly prescriptive and proposed to allow establishments to devise their own means for limiting microbial growth in their processing operations. Commenters claimed that the prescriptive temperature requirement is imperative for preventing microbial growth and contended that small establishments lack the resources and expertise to innovate in this area.

*Response:* As stated in the proposal, in response to requests, FSIS has permitted many establishments to use methods other than reducing ambient temperature to control microbial growth in raw poultry. Several establishments have used heat-exchangers connected to the grinding equipment to bring about an immediate reduction in product temperature. Use of heat-exchangers on the equipment can more effectively reduce product temperature and limit growth of microorganisms than strict adherence to the requirement to maintain a specific room temperature. The performance standard for operational sanitation will allow establishments to devise their own means for limiting microbial growth in their processing operations, without requesting special approval from the Agency.

Small establishments will not have to innovate in this area. If they choose, small establishments may continue to maintain the temperature in poultry deboning rooms at 50 °F. Since this measure has been proven to adequately control microbial growth in this processing situation, it will continue to meet the performance standard for operational sanitation, until new or better data suggest otherwise.

*Comment:* Also in regard to operational sanitation, FSIS proposed the following performance standard: “Product must be protected from contamination or adulteration during processing, handling, storage, loading, and unloading at and during

transportation from official establishments; ready-to-eat product must be protected from cross-contamination by pathogenic organisms." Several commenters argued that the standard regarding cross-contamination of ready-to-eat product was redundant, unnecessary, and only an example of one kind of product adulteration. They requested that FSIS make final only the first, more general standard.

*Response:* FSIS agrees that the proposed standard concerning cross-contamination is redundant and thus, for clarity, will not finalize it. Establishments already are specifically required to prevent the cross-contamination of ready-to-eat product by the first half of this proposed standard. FSIS also is revising this standard by removing the prohibition against product contamination, because, as explained above, such a standard is unnecessary.

#### *Employee Hygiene: Proposed § 416.5(a)*

*Comment:* Several commenters argued that the proposed performance standards for employee hygiene were too prescriptive. Specifically, these commenters objected to the proposed requirement that "All persons working in contact with \* \* \* product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product." They maintained that insanitary contact with certain packaging materials, such as canned product shipping containers, could never lead to product adulteration. These commenters suggested that FSIS clarify that the standard only applies to "product-contact-packaging."

*Response:* Although the unhygienic handling of certain packaging materials that do not come in contact with product may not lead to direct contamination of the product contained therein, such handling could contribute to the creation of insanitary conditions within an official establishment. FSIS is revising the performance standard to reflect this concern. The finalized § 416.5(a) states: "All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions."

*Comment:* Conversely, several commenters opposed rescinding the existing regulatory prohibitions against specific, unhygienic employee activities and replacing them with performance standards. As discussed above in the "General Opposition" section, these

commenters asserted that FSIS inspection program employees' enforcement authority will be weakened without specific prohibitions against such actions as "placing skewers, tags, or knives in the mouth" (§ 308.8(e)). Further, these commenters cited multiple anecdotal examples of employee actions that could lead to the adulteration of product.

*Response:* FSIS does not need to specifically enumerate every action by establishment personnel that could possibly lead to product adulteration or insanitary conditions. It would, in fact, be impossible to compile such a list of prohibited practices. FSIS program employees have always had the authority, and will continue to have the authority, to take action whenever establishment personnel fail to ensure that product is not adulterated or fail to maintain sanitary conditions, even if the problem identified is not specifically delineated in a regulation. This authority remains unchanged under the new performance standard for employee hygiene in § 416.5(a).

#### *Employee Clothing: Proposed § 416.5(b)*

*Comment:* FSIS proposed a performance standard requiring that all employee outer clothing be readily cleanable. Several commenters from industry stated that their employees use disposable clothing, which is both sanitary and cost-effective, and requested that FSIS revise the standard to specifically allow for the use of disposable clothing.

*Response:* FSIS agrees that disposable clothing can be appropriately sanitary and has revised the standard to read, in part: "Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned."

#### *Employee Disease: Proposed § 416.5(c)*

*Comment:* FSIS proposed a performance standard requiring that:

Any person who has or appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination must be excluded from any operations which could result in product contamination or adulteration until the condition is corrected.

One commenter requested that the word "illness" be replaced with the word "disease."

*Response:* FSIS agrees and has replaced the word "illness" with the phrase "infectious disease." "Illness" is a general term that could describe a disease or condition that is not infectious and therefore would pose no risk of product adulteration. The phrase

"contamination or" also is removed for reasons explained above.

#### *Tagging Insanitary Equipment, Utensils, Rooms or Compartments: Proposed § 416.6*

*Comment:* In regard to tagging insanitary equipment, utensils, rooms or compartments, FSIS proposed that its inspection program employees take such action when they find "that any equipment, utensil, room, or compartment at an official establishment is unclean or that its use would be in violation of any of the regulations in this subchapter." Several commenters objected to the word "unclean," arguing that it constituted a new standard and that its vagueness would lead to highly subjective enforcement by FSIS inspection program employees.

*Response:* The proposed language is not new and, in fact, is almost identical to the previous tagging regulation, § 308.15. Nevertheless, FSIS agrees that the regulation can be improved and for consistency with the sanitation requirements has replaced the word "unclean" with the word "insanitary." As stated above, under the FMIA and PPIA, FSIS must take action when an official establishment operates in a manner that leads to insanitary conditions and product adulteration. Accordingly, FSIS is revising the requirement to state that an FSIS inspection program employee will tag equipment, utensils, rooms, or compartments at an official establishment if they are "insanitary or [their] use could cause the adulteration of product."

#### *Custom Slaughter Establishments*

*Comment:* One commenter suggested that the proposed revisions to language exempting custom establishments from certain sanitation requirements were too restrictive, as they would apply only to custom slaughter operations and not to custom processing operations.

*Response:* FSIS agrees. This error was unintentional and the exemption in § 303.1(a)(2)(i) has been revised so as to apply to establishments "that conduct custom operations," rather than only to "establishments conducting custom slaughter operations."

#### *Miscellaneous Changes*

In the proposal preceding this final rule, FSIS stated that it needed "to revise all of the cross-references in the meat and poultry regulations to reflect the proposed deletion of Part 308 and 381 Subpart H and the proposed addition of new §§ 416.1 through 416.6." FSIS is making those revisions

in this final rule. References to specific sanitation requirements contained in sections of previous Part 308 or 381 Subpart H are replaced with references to the relevant sanitation performance standards in Part 416.

FSIS also is making a few revisions to the regulations for consistency with the new sanitation performance standards. Although FSIS did not propose these specific revisions, they are necessary to avoid conflict within the meat and poultry inspection regulations. These changes will impose no new regulatory burden on establishments.

First, Section 381.36(c)(1)(viii) of the poultry regulations states that "Online handrinsing facilities with a continuous flow of water conforming to section 381.51(f) shall be provided for and within easy reach of each inspector and each establishment helper." Section 381.51(f), which will be deleted by this final rule, stated:

An adequate number of hand washing facilities shall be provided in areas where poultry products are prepared. Hand washing facilities accepted in accordance with the procedures set forth in section 381.53 may be used in such areas, provided that if hand-activated facilities are used, the hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

Although FSIS is deleting from § 381.36(c)(1)(viii) the reference to the deleted § 381.51(f), it is not rescinding the requirements for hand washing facilities at inspection stations in official poultry establishments. The specific requirements for hand washing equipment and water temperatures previously contained in § 381.51(f) are now contained in § 381.36(c)(1)(viii). Similarly, in this final rule, although FSIS is replacing with a performance standard the prescriptive light intensity requirements for official poultry establishments (previous § 381.52), it is not rescinding the specific light intensity requirements for inspector and reprocessing stations currently contained in §§ 307.2 and 381.36. FSIS has determined that although official establishments are responsible for determining what light intensities and types of hand washing equipment are necessary to maintain sanitary conditions, the specific requirements for light intensities and hand washing facilities at inspection stations are still

necessary to ensure appropriate conditions for effective inspection.

Second, FSIS is revising the regulations in §§ 314.2 and 314.4 regarding the adulteration of edible meat and poultry product by inedible meat and poultry products. Specifically, FSIS is removing references to Part 308 and converting to performance standards prescriptive requirements regarding the prevention of product adulteration through contact with inedible product or odors from inedible product. These revisions are entirely consistent with the performance standards for establishment construction, operations, and the suppression of odors.

#### *Elimination of Directives*

*Comment:* Several commenters objected to the proposed rescission of numerous FSIS Directives and Issuances concerning sanitation in official establishments, particularly FSIS Directive 11,000.1, the "Sanitation Handbook for Meat and Poultry Inspection." These commenters claimed that these Directives are needed by FSIS inspection program employees to ensure that establishments maintain adequate sanitation and do not adulterate product.

*Response:* The FSIS Issuances and Directives in question are based upon the prescriptive sanitation regulations that are being rescinded and replaced by this rule. Therefore, retention of these documents would only generate conflict and confusion regarding the sanitation requirements official establishments must meet and how FSIS inspection program employees are to enforce these new requirements. For consistency with the HACCP and Sanitation SOP requirements and with the recent elimination of prior approval of establishment blueprints and equipment, FSIS already has rescinded the following Directives concerning sanitation (FSIS Notice 3-98; January 16, 1998):

FSIS Directive 7110.4—Liquid Smoke Re-Use  
 FSIS Directive 11,100.1—Sanitation Handbook  
 FSIS Directive 11,000.2—Plant Sanitation  
 FSIS Directive 11,000.4—Paints and Coatings in Official Establishments  
 FSIS Directive 11,210.1—Protecting Potable Water Supplies on Official Premises  
 FSIS Directive 11,220.2—Guidelines for Sanitization of Automatic Poultry Eviscerating Equipment  
 FSIS Directive 11,520.2—Exposed Heat-Processed Products; Employee Dress

Further, in a forthcoming FSIS Directive concerning the new performance standards, FSIS will rescind these remaining Directives:

FSIS Directive 11,240.5—Plastic Cone Deboning Conveyors  
 FSIS Directive 11,520.4—Strip Doors in Official Establishments  
 FSIS Directive 11,540.1—Use of Certain Vehicles as Refrigeration or Dry Storage Facilities  
 MPI Bulletin 77-34—Chemical Disinfection in Lieu of 180 deg. °F Water  
 MPI Bulletin 77-129—Water Conservation and Sanitation  
 MPI Bulletin 79-68—Use of Iodine in Processing Water  
 MPI Bulletin 81-38—Equipment and Procedure Requirements for Processing Gizzards  
 MPI Bulletin 83-14—Monitoring Chlorine Concentration in Official Establishments  
 MPI Bulletin 83-16—Re-Use of Water or Brine Cooking Solution on Product Following a Heat Treatment

As stated above, FSIS is issuing a new Sanitation Directive to accompany this rule. Although the Directive is written for FSIS inspector program employees, it will be available to the public. In addition, FSIS also will be issuing a compliance guide to assist establishments in complying with the new sanitation performance standards.

#### *Compliance With Executive Order 12866 and the Regulatory Flexibility Act of 1996*

This rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

FSIS is revising and consolidating the sanitation regulations for official meat and poultry establishments, resolving unnecessary differences between similar rules for meat and poultry processing, and converting prescriptive requirements to performance standards. This action affects meat and poultry establishments subject to official inspection, custom exempt meat and poultry establishments, and consumers. In the proposal preceding this final action, FSIS requested comment concerning the potential economic effects of the proposed sanitation performance standards. FSIS specifically requested information that would allow the Agency to determine the number and kind of small entities that may incur benefits or costs resulting from issuance of this final rule.

FSIS received no comments that specifically addressed this issue. However, several commenters opposed

to the proposed sanitation performance standards maintained that small meat and poultry establishments do not have the resources to innovate in order to take advantage of the flexibility provided by the performance standards. Further, these commenters argued that small establishments need prescriptive requirements to ensure that they know how to maintain sanitary conditions and produce safe, unadulterated products. FSIS disagrees. Establishments currently maintaining sanitary conditions may choose to continue their current practices and be assured that they will be found in compliance with the new performance standards. In addition, FSIS will be making available a compliance guide that will contain much of the information contained in previous sanitation regulations and Directives, to assist establishments of all sizes in meeting the new sanitation performance standards.

In general, the streamlining, clarification, and consolidation of the sanitation regulations should benefit FSIS, the regulated industry, and consumers. User-friendly regulations employing performance standards simplify compliance and, therefore, should bring about food safety enhancements in individual establishments. Further, consolidation of the separate sanitation requirements for meat and poultry establishments and the consequent elimination of unnecessary inconsistencies will better ensure that enforcement policies are consistent and equitable and that competition is enhanced.

The performance standards allow individual establishments to develop and implement customized sanitation procedures other than those currently mandated, as long as those procedures produce and maintain sanitary conditions that meet the performance standards. Establishments taking advantage of the performance standards to innovate may benefit from savings accrued through increased efficiency. Since the previously mandated sanitation procedures meet the performance standards established by this final rule, establishments may continue employing their current procedures. There is no discernable reason that establishments would incur any additional expenses as a result of this rule. As a matter of fact, FSIS anticipates that the adoption of these sanitation performance standards will present numerous opportunities for cost savings and believes that this rule will have a favorable economic impact on all establishments, regardless of size.

It is difficult to quantify the potential benefits of the sanitation performance

standards since it is not possible to predict exactly how many establishments will take advantage of the flexibility provided and develop innovative processes and how these innovations will reduce costs and increase efficiency. However, FSIS sees the potential for a more efficient use of resources by official establishments. Also, the possibility of subsequently reduced prices of meat or poultry products are economic factors that could produce a more efficient use of resources in the economy as a whole. These effects would be small for individual firms and consumers, but could be substantial in the aggregate.

Finally, FSIS is restructuring inspection activities to focus more attention on whether establishments maintain a sanitary environment in accordance with the Sanitation SOP requirements and these sanitation performance standards. This action should reduce demands on FSIS resources which could be redirected to functions more critical to improving food safety. FSIS anticipates that this restructuring of inspection, along with these performance standards and the HACCP, Sanitation SOP, and other food safety initiatives, will produce significant economic and societal benefits by reducing the incidence of food borne illness.

In response to comments, FSIS is finalizing a new requirement in regard to the use of nonfood compounds and proprietary substances in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since the specific documentation substantiating the safety of a chemical will almost certainly vary as to the nature and use of that chemical. Most, if not all, of the nonfood compounds and proprietary substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Pesticides, for example, have labels and documentation demonstrating registration with EPA; chemical sanitizers used on food contact surfaces often are accompanied by documentation, such as letters of guarantee, stating that the compound complies with the relevant FDA regulations in 21 CFR 178.1010. Therefore, FSIS has concluded that the finalized documentation requirement will place no new economic burden on

the manufacturers or consumers of most of these compounds.

FSIS recognizes that certain compounds, such as general cleaners and antislip agents, are not currently regulated or reviewed by any Federal agency and therefore may not be sold with documentation attesting to the safety and efficacy of their use in food processing establishments. Manufacturers will be compelled, therefore, to make such documentation available to their customers, if they are not doing so already. However, FSIS estimates that the economic impact of this requirement on these manufacturers will be minimal. Until the recent discontinuation of the FSIS prior approval program, these manufacturers had been required to supply FSIS with documentation attesting to the safety of their products. Now they will instead make this or similar documentation available to their customers. The paperwork burden of this new documentation requirement is discussed below under the section *Paperwork Requirements*.

As an alternative to the proposed sanitation performance standards, the Agency considered proposing more comprehensive and prescriptive sanitation regulations. The proposed requirements would then have included more prescriptive performance standards than those proposed, such as microbial criteria for recently cleaned and sanitized food contact surfaces; detailed requirements currently contained in Agency guidance materials, such as an ambient temperature requirement for rooms in which certain types of food processing are conducted; and a list of specific regulatory prohibitions, again largely drawn from existing regulatory and guidance material.

The Agency did not choose this more detailed and prescriptive alternative, because of the burden it would place on industry. The Agency believes that a proliferation of prescriptive standards applicable to the establishment environment or its features, like ambient temperature or microbial characteristics of cleaned equipment, would not be a useful addition to the sanitation performance standards.

FSIS already has established performance standards applicable to meat and poultry products, such as the Salmonella performance standard for raw carcasses and ground product established in the Pathogen Reduction/HACCP final regulation and the zero tolerance standard for fecal material on raw carcasses. Achieving these product-based performance standards depends on an establishment doing a number of

things correctly, including meeting the sanitation performance standards set forth in part 416.1 through 416.6. FSIS has concluded that because there are many methods and means through which establishments can ensure that products are not adulterated, FSIS will not prescribe exactly which methods, procedures, or means must be used.

Finally, on the issue of whether there should be a list of specific prohibited practices retained in the regulations, FSIS has concluded that this is not necessary and that such a list could be misleading. Most of the prohibited practices that are mentioned in the current sanitation regulations represent only one or a small fraction of the ways in which establishments could fail to meet a performance standard. For example, using burlap as a wrap by directly applying it to the surface of meat is only one of the means by which an establishment could be failing to prevent product adulteration. The Agency believes that a partial or outdated list of regulatory prohibitions in the regulations could be misconstrued to mean that anything not on the list is not prohibited. FSIS has concluded that it is better regulatory policy to communicate to industry examples of the types of practices that could result in insanitary conditions in guidance material.

The other alternative available to FSIS was to maintain the previous sanitation requirements. However, as explained in detail above, these requirements were to an extent inconsistent with the principles of HACCP, needlessly reduced flexibility in accomplishing good sanitation, and may have substantially impeded innovation.

#### *Executive Order 12898*

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," FSIS has considered potential impacts of this final rule on environmental and health conditions in low-income and minority communities.

This rule consolidates the sanitation regulations for official meat and poultry establishments into a single part, eliminates unnecessary differences between the meat and poultry sanitation requirements, and converts many highly prescriptive requirements to sanitation performance standards. As explained in the economic impact analysis above, the new regulations should generally benefit FSIS, the regulated industry, and consumers. The regulations do not require or compel meat or poultry establishments to relocate or

significantly alter their operations in ways that could adversely affect the public health or environment in low-income and minority communities. Further, this rule does not exclude any persons or populations from participation in FSIS programs, deny any persons or populations the benefits of FSIS programs, or subject any persons or populations to discrimination because of their race, color, or national origin.

#### *Executive Order 12988*

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This rule is not intended to have retroactive effect.

Under this rule, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to any matters under the FMIA and the PPIA.

#### *Paperwork Requirements*

**Abstract:** FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act.

Under the previous regulations, if meat and poultry establishments were cited for rodent or vermin infestation, FSIS required them to develop a written corrective action report. The Office of Management and Budget (OMB) under control number O583-0082, "Meat and Poultry Inspection and Application for Inspection," had approved 351 burden hours for this activity.

This final rule eliminates the requirement that establishments develop rodent and vermin infestation corrective action reports. Corrective action measures for rodent and vermin infestation will be part of establishments' Sanitation SOP's. The burden hours reported for Sanitation SOP's includes the development of these corrective actions. Therefore, FSIS is requesting OMB to remove the 351 burden hours approved for the development of rodent and vermin infestation corrective action reports.

Also, § 416.2(g)(1) requires that establishments, upon request, make available to FSIS "water reports issued under the authority of the State or local health agency certifying or attesting to the quality of the water supply." This paperwork collection requirement already is in place under the current regulations and is approved under OMB control number O583-0082, "Meat and Poultry Inspection and Application for Inspection."

Finally, the Agency is adding a new information collection requirement in § 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since documentation substantiating the safety of a chemical varies as to the nature and use of that chemical. Further, most, if not all, of the nonfood compounds and proprietary substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Nevertheless, manufacturers will be compelled to make such documentation available to their customers, if they are not doing so already. FSIS estimates that the impact of this requirement on these manufacturers will be quite minimal, since until the recent discontinuation of the FSIS prior approval program, these manufacturers had been required to supply FSIS with documentation attesting to the safety of their products.

FSIS estimates that there are approximately 8,000 chemical manufacturers selling about 115,000 compound and substances to official meat and poultry establishments. There are approximately 6,186 official meat and poultry establishments. The following calculations were based upon the assumption that each chemical manufacturer sells, and each official establishment uses, an average of 14 compounds and substances.

**Estimate of Burden:** The public reporting burden for this collection of



information is estimated to average 30 minutes for chemical manufacturers to provide documentation and 10 minutes for establishments to file the information.

*Respondents:* Meat and poultry establishments and chemical manufacturers.

*Estimated Number of Respondents:* 14,186.

*Estimated Number of Responses per Respondent:* 14.

*Estimated Total Annual Burden on Respondents:* 132,403 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Cotton Annex Building, Room 109, Washington, DC 20250.

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 will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, Paperwork Specialist (see address above) or the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by December 20, 1999. To be most effective, comments should be sent to OMB within 30 days of the publication date of this final rule.

#### List of Subjects

9 CFR Parts 303, 304, and 307

Meat inspection, Reporting and record keeping requirements.

9 CFR Part 308, 312, 314, 327,, 331, and 350

Meat inspection.

9 CFR Part 381

Poultry and poultry products inspection, Reporting and record keeping requirements.

9 CFR Part 416

Sanitation.

Accordingly, title 9, chapter III, of the Code of Federal Regulations is amended as follows:

#### PART 303—EXEMPTIONS

1. The authority citation for part 303 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 303.1 is amended by revising paragraph (a)(2)(i) to read as follows:

##### § 303.1 Exemptions.

- (a) \* \* \*
- (2) \* \* \*

(i) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§ 416.1 through 416.6, except for: § 416.2(g) (2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter of shall apply to those operations.

\* \* \* \* \*

##### § 303.1 [Amended]

3. In § 303.1, paragraph (c), the second sentence is amended by removing the phrase “in part 308 of this subchapter, except §§ 308.1, 308.2, and 308.15” and adding the phrase “in part 416, §§ 416.1 through 416.5 of this chapter” in its place.

#### PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

4. The authority citation for part 304 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

##### § 304.2 [Amended]

5. In § 304.2(b), the first sentence is amended by removing the phrase “308” and adding the phrase “Part 416, §§ 416.1 through 416.6 of this chapter” in its place.

#### Part 307—FACILITIES FOR INSPECTION

6. The authority citation for part 307 continues to read as follows:

**Authority:** 7 U.S.C 394, 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

7. Section 307.2 is amended by revising paragraph (l) to read as follows:

##### § 307.2 Other facilities and conditions to be provided by the establishment.

\* \* \* \* \*

(l) Sanitary facilities and accommodations as prescribed by §§ 416.2(c), (d), (e), (f), and (h) of this chapter.

\* \* \* \* \*

8. Section 307.3 is revised to read as follows:

##### § 307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by § 416.3(a) of this chapter.

9. Section 307.7, paragraph (a), is revised to read as follows:

##### § 307.7 Safety requirements for electrical stimulating (EST) equipment.

(a) *General.* Electrical stimulating (EST) equipment is equipment that provides electric shock treatment to carcasses for the purpose of accelerating rigor mortis of facilitating blood removal. These provisions do not apply to electrical equipment used to stun and/or slaughter animals or to facilitate hide removal. Electrical stimulating equipment consists of two separate pieces—the control system and the applicator. The EST control system contains the circuitry to generate pulsed DC or AC voltage for stimulation and is separate from the equipment used to apply the voltage to the carcass. The voltage is applied by inserting a probe that penetrates the carcass or is inserted in the rectum, placing a clamp in the nose, a carcass rub-bar, a conveyor with energized surfaces traveling with the carcass, or any other acceptable method.

\* \* \* \* \*

#### PART 308—[REMOVED AND RESERVED]

10–11. Remove and reserve part 308, consisting of §§ 308.1–308.16.

#### PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

12. The authority citation for part 312 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

13. In § 312.6, paragraphs (a), and introductory text and (a)(3) are revised to read as follows:



**§ 312.6 Official marks and devices in connection with post-mortem inspection and identification of adulterated products and insanitary equipment and facilities.**

(a) The official marks required by parts 310 and 416 of this chapter for use in post-mortem inspection and identification of adulterated products and insanitary equipment and facilities are:

\* \* \* \* \*

(3) The "U.S. Rejected" mark which is used to identify insanitary buildings, rooms, or equipment as prescribed in part 416, § 416 of this chapter and is applied by means of a paper tag (Form MP-35) bearing the legend "U.S. Rejected."

\* \* \* \* \*

**PART 314—HANDLING AND DISPOSAL OF CONDEMNED OR OTHER INEDIBLE PRODUCTS AT OFFICIAL ESTABLISHMENTS**

14. The authority citation for part 314 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

15. Section 314.2 is revised to read as follows:

**§ 314.2 Tanking and other facilities for inedible products to be separate from edible product facilities.**

All tanks and equipment used for rendering, otherwise preparing, or storing inedible products must be in rooms or compartments separate from those used for preparing or storing edible products. There may be a connection between rooms or compartments containing inedible products and those containing edible products as long as it does not cause the adulteration of edible product or create insanitary conditions.

16. Section 314.4 is revised to read as follows:

**§ 314.4 Suppression of odors in preparing inedible products.**

Tanks, fertilizer driers, and other equipment used in the preparation of inedible product must be operated in a manner that will suppress odors incident to such preparation which could adulterate edible product or create insanitary conditions.

**PART 327—IMPORTED PRODUCTS**

17. The authority citation for part 327 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

**§ 327.6 [Amended]**

18. In § 327.6, paragraph (e) is amended by removing the phrase "

308.3, 308.4, 308.5, 308.6, 308.7, 308.8, 308.9, 308.11, 308.13, 308.14, 308.15" and adding the phrase "416.1 through 416.6 of this chapter" in its place.

**PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS**

19. The authority citation for part 331 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

20. Section 331.3, paragraph (c), is revised to read as follows:

**§ 331.3 States designated under paragraph § 301(c) of the Act; application of regulations.**

\* \* \* \* \*

(c) Sections 416.2(c), (d), (e), (f), and (h) of this chapter shall apply to such establishments.

\* \* \* \* \*

**PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS**

21. The authority citation for part 350 continues to read as follows:

**Authority:** 21 U.S.C. 1622, 1624; 7 CFR 2.17, 2.55.

**§ 350.3 [Amended]**

22. Section 350.3, paragraph (a)(2) is amended by removing the phrase "part 308" and adding the phrase "part 416, §§ 416.1 through 416.6 of this chapter" in its place.

**PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS**

23. The authority citation for part 362 continues to read as follows:

**Authority:** 21 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

**§ 362.2 [Amended]**

24. The second sentence of § 362.2(a) is amended by removing the phrase "subchapter C of this chapter" and adding the phrase "subchapter A and subchapter E, part 416, §§ 416.1 through 416.6 of this chapter" in its place.

**PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS**

25. The authority citation for part 381 continues to read as follows:

**Authority:** 7 U.S.C. 138f; 7 U.S.C. 450, 21 U.S.C. 451–470; 7 U.S.C. 2.18, 2.53.

26. In § 381.1, paragraph (b)(39) is removed.

27. Section 381.36, is amended as follows:

a. Paragraph (c)(1)(iv) is revised,  
b. Paragraph (c)(1)(vi), is amended by removing the phrase "complying with § 381.53(g)(4) of this part",

c. Paragraphs (c)(1)(vii), (viii) and (x) are revised,

d. In Paragraph (d)(1)(vi), the first sentence is amended by removing the phrase "complying with § 381.53(g)(4) of this part",

e. In paragraph (d)(1)(viii), the first sentence is amended by removing the phrase "notwithstanding the requirement of § 381.52(b)",

f. Paragraph (d)(1)(xi) is revised,  
g. In paragraph (e)(1)(v), the first sentence is amended by removing the phrase "complying with § 381.53(g)(4)", and

h. Paragraph (e)(1)(ix) is revised.

These revisions to § 381.36 read as follows:

**§ 381.36 Facilities required.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

\* \* \* \* \*

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such

inspection stations at a minimum temperature of 65 degrees F.

(ix) \* \* \*

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(xi) Each inspection station shall be provided with receptacle for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

\* \* \* \* \*

#### §§ 381.45–381.61 (Subpart H)—Sanitation [Removed and reserved]

28. Remove and reserve Subpart H, consisting of §§ 381.45–381.61.

29. Section 381.99 is revised to read as follows:

#### § 381.99 Official retention and rejection tags.

The official marks for use in post-mortem inspection and identification of adulterated products, insanitary equipment and facilities are:

(a) A paper tag (a portion of Form MP-35) bearing the legend "U.S. Retained" for use on poultry or poultry products under this section.

(b) A paper tag (another portion of Form C&MS 510) bearing the legend "U.S. Rejected" for use on equipment, utensils, rooms and compartments under this section.

#### PART 416—SANITATION

30. The authority citation for part 416 continues to read as follows:

**Authority:** 21 U.S.C. 451–470, 601–680; 7 U.S.C. 450; 7 CFR 2.18, 2.53.

31. Part 416 is amended by adding new §§ 416.1 through 416.6, as follows:

#### § 416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

#### § 416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) *Construction.* (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) *Ventilation.* Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) *Plumbing.* Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

(f) *Sewage disposal.* Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and water, ice, and solution reuse.* (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological

contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) *Dressing rooms, lavatories, and toilets.* (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

#### **§ 416.3 Equipment and utensils.**

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate

thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

#### **§ 416.4 Sanitary operations.**

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

#### **§ 416.5 Employee hygiene.**

(a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean

garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

#### **§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.**

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

Done in Washington, DC on October 6, 1999.

**Thomas J. Billy,**  
*Administrator.*

[FR Doc. 99-26983 Filed 10-19-99; 8:45 am]  
BILLING CODE 3410-DM-P

## **DEPARTMENT OF ENERGY**

### **10 CFR Part 600**

#### **RIN 1991-AB53**

### **Assistance Regulations; Technical and Administrative Amendments**

**AGENCY:** Department of Energy.

**ACTION:** Final rule.

**SUMMARY:** The Department of Energy (DOE) is amending the Department of Energy Assistance Regulations to make technical and administrative changes. These changes include: revising a definition for clarity, updating titles and addresses, changing an approval authority, eliminating provisions that contain internal procedures for DOE officials, removing obsolete coverage, eliminating redundant coverage, and correcting a typographical error. These changes are technical and administrative in nature and have no significant impact on non-agency persons, such as recipients or applicants. The uniform administrative requirements for grants and cooperative agreements with institutions of higher

education, hospitals, other non-profit organizations, commercial organizations, and state and local governments are not changed by this rule.

**EFFECTIVE DATE:** This final rule will be effective November 19, 1999.

**FOR FURTHER INFORMATION CONTACT:**

Trudy Wood, Office of Procurement and Assistance Policy (MA-51), U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585, telephone 202-586-5625.

**SUPPLEMENTARY INFORMATION:**

I. Explanation of Changes

II. Procedural Requirements

- A. Review Under Executive Order 12866
- B. Review Under Executive Order 12988
- C. Review Under the Regulatory Flexibility Act
- D. Review Under the Paperwork Reduction Act
- E. Review Under the National Environmental Policy Act
- F. Review Under Executive Order 12612
- G. Review Under the Unfunded Mandates Reform Act of 1995
- H. Review Under the Treasury and General Government Appropriations Act, 1999

**I. Explanation of Changes**

1. In section § 600.3 *Definitions*, we have revised the definition of "Merit review" to clarify what constitutes an "independent examination" of a financial assistance application.

2. In § 600.4 *Deviations*, we have updated the title of the authorizing official.

3. In § 600.6 *Eligibility*, we have changed the approval authority on a determination that a noncompetitive award is in the public interest to the Secretary, because such determinations are more appropriately made by the Secretary of Energy.

4. In § 600.10 *Form and content of applications*, we have updated the address for obtaining a guide for the preparation and submission of unsolicited applications and removed redundant language.

5. In § 600.13 *Objective merit review*, we have changed the title to "Merit review" and eliminated provisions relating to internal procedures that are more appropriately addressed in a DOE handbook on merit reviews.

6. Section 600.14 *Conflict of interest* is removed because the current provision is obsolete. Conflict of interest requirements for all DOE employees, including those who participate in the review of applications for DOE financial assistance or in the administration of financial assistance awards, are covered in 5 CFR part 2635 and part 2640. Conflict of interest requirements for non-federal merit reviewers are more

appropriately covered in a DOE handbook on merit reviews.

7. In § 600.24 *Noncompliance*, we have corrected a typographical error in a cross-reference.

**II. Procedural Requirements**

**A. Review Under Executive Order 12866**

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Accordingly, this action is not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

**B. 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 (February 7, 1996)" 61 FR 4729, 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. The Department of Energy has completed the required review and determined that, to the extent permitted by law, the regulations meet the relevant standards of Executive Order 12988.

**C. Review Under the Regulatory Flexibility Act**

This rule is not subject to review under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because there is no

legal requirement to propose financial assistance rules for public comment.

**D. Review Under the Paperwork Reduction Act**

No new information or recordkeeping requirements are imposed by this rulemaking. Accordingly, no OMB clearance is required under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

**E. Review Under the National Environmental Policy Act**

DOE has concluded that promulgation of this rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by DOE's regulations (10 CFR part 1021, subpart D) implementing the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). Specifically, this rule is categorically excluded from NEPA review because the proposed amendments to the DOE financial assistance regulation do not change the environmental effect of the rule being amended (categorical exclusion A.5). Therefore, this rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

**F. Review Under Executive Order 12612**

Executive Order 12612 (52 FR 41685, October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among the various levels of Government. If there are sufficient substantial direct effects, then the Executive Order requires the preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action. DOE has determined that this rule will not have a substantial direct effect on the institutional interests or traditional functions of the States.

**G. Review Under the Unfunded Mandates Reform Act of 1995**

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) generally requires a Federal agency to perform a detailed assessment of costs and benefits of any rule imposing a Federal Mandate with costs to state, local or tribal governments, or to the private sector, of \$100 million or more. This rulemaking would not affect state, local or tribal governments or private sector entities.

*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 or policy that may affect family well-being. This rulemaking is not subject to a requirement to propose for public comment, and section 654 therefore does not apply.

**List of Subjects in 10 CFR Part 600**

Administrative practice and procedure.

Issued in Washington, DC, on October 12, 1999.

**Richard H. Hopf,**

*Director, Office of Procurement and Assistance Management.*

For the reasons set out in the preamble, part 600 of Chapter II, Title 10 of the Code of Federal Regulations, is amended as follows:

**PART 600—FINANCIAL ASSISTANCE RULES**

1. The authority citation for part 600 continues to read as follows:

**Authority:** 42 U.S.C. 7254, 7256, 13525; 31 U.S.C. 6301-6308, unless otherwise noted.

2. Section 600.3 is amended by removing the term *objective merit review* and adding in its place in alphabetical order the term *merit review* to read as follows:

**§ 600.3 Definitions.**

*Merit review* means a thorough, consistent, and objective examination of applications based on pre-established criteria by persons who are independent of those submitting the applications and who are knowledgeable in the field of endeavor for which support is requested.

\* \* \* \* \*

**§ 600.4 [Amended]**

3. Section 600.4 is amended in paragraphs (c)(2)(ii) and (c)(3) by revising the phrase "Deputy Assistant Secretary for Procurement and Assistance Management" to read "Director, Procurement and Assistance Management".

4. Section 600.6 is amended by revising paragraph (c)(8) to read as follows:

**§ 600.6 Eligibility.**

\* \* \* \* \*

(c) \* \* \*

(8) The responsible program Assistant Secretary (or official of equivalent

authority), with the approval of the Secretary of Energy, determines that a noncompetitive award is in the public interest. This authority may not be delegated.

\* \* \* \* \*

5. Section 600.10 is amended by revising paragraph (b) to read as follows:

**§ 600.10 Form and content of applications.**

\* \* \* \* \*

(b) *Forms.* Applications shall be on the form and in the number of copies specified in a program rule, the solicitation, or these regulations. (See also §§ 600.112 and 600.210.) For unsolicited applications, a guide for preparation and submission is available from U.S. Department of Energy, Federal Energy Technology Center, Attn: Unsolicited Proposal Manager, Post Office Box 10940, Pittsburgh, PA, 15236-0940.

\* \* \* \* \*

6. Section 600.13 is revised to read as follows:

**§ 600.13 Merit review.**

\* \* \* \* \*

(a) It is the policy of DOE that discretionary financial assistance be awarded through a merit-based selection process. A merit review means a thorough, consistent, and objective examination of applications based on pre-established criteria by persons who are independent of those submitting the applications and who are knowledgeable in the field of endeavor for which support is requested.

(b) Each program office must establish a merit review system covering the financial assistance programs it administers. Merit review of financial assistance applications is intended to be advisory and is not intended to replace the authority of the project/program official with responsibility for deciding whether an award will be made.

**§ 600.14 [Removed and Reserved]**

7. Section 600.14 is removed.

**§ 600.24 [Amended]**

8. Section 600.24 is amended in paragraph (b), introductory text, by revising "§ 600.121(n)" to read "§ 600.122(n)".

[FR Doc. 99-27424 Filed 10-19-99; 8:45 am]

BILLING CODE 6450-01-P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. 98-NM-338-AD; Amendment 39-11380; AD 99-22-02]

RIN 2120-AA64

**Airworthiness Directives; Boeing Model 757-200PF Series Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to all Boeing Model 757-200PF series airplanes, that requires revising the Airplane Weight & Balance (W&B) Manual to prohibit operation of any airplane without side vertical restraints installed on the main cargo deck when carrying a particular pallet. This amendment also provides for optional terminating action for the Airplane W&B Manual revision. This amendment is prompted by reports indicating that some airplanes have been operated without side vertical restraints installed on the main cargo deck when carrying certain pallets. The actions specified by this AD are intended to prevent inadvertent movement of a cargo pallet during flight, which could result in an adverse center of gravity condition and consequent reduced controllability of the airplane.

**EFFECTIVE DATE:** November 24, 1999.

**ADDRESSES:** Information pertaining to this amendment may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington.

**FOR FURTHER INFORMATION CONTACT:** James G. Rehrl, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2783; fax (425) 227-1181.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Boeing Model 757-200PF series airplanes was published in the **Federal Register** on February 10, 1999 (64 FR 6577). That action proposed to require revising the Airplane Weight & Balance (W&B) Manual to prohibit operation of any airplane without side vertical restraints installed on the main cargo deck when

carrying a particular pallet. That action also proposed to provide for optional terminating action for the Airplane W&B Manual revision.

#### Comments

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

#### Support for the Proposal

One commenter supports the proposed rule, and another states that it has no comment.

#### Request for Extension of the Compliance Time

One commenter requests that the compliance time for the actions required by this proposed AD be extended to at least 28 months after the airplane manufacturer provides a service bulletin to modify the airplanes to install side vertical restraints. The commenter states that, in 12 years of operating with Type II cargo pallets, it has never had an adverse incident. The commenter states that this proposed AD would have an enormous effect on its fleet because it will have to use Type I cargo pallets. The commenter states that Type I cargo pallets are not readily available and, because other operators with which the commenter interacts do not use Type I cargo pallets, it will be difficult to use the services of Model 757-200PF series airplanes.

The FAA concurs that the compliance time can be extended somewhat. The FAA does not intend for this AD to place undue hardship on the affected operators. Based on the information provided by the commenter, the FAA now recognizes that a compliance time of 28 months would better allow operators to purchase Type I cargo pallets or make the necessary modifications to airplanes to resume use of Type II cargo pallets. In addition, a compliance time of 28 months is identical to the compliance times for similar actions to correct similar identified unsafe conditions on other transport category cargo airplanes. Paragraph (a) of the final rule has been revised accordingly.

#### Request for Use of Modified Type II Cargo Pallets

One commenter requests that the proposed AD be revised to allow the use of modified Type II cargo pallets that meet the NAS3610 requirements. The commenter states that the problem with the Type II cargo pallets is that they are too flexible, but that the pallets could be

manufactured with acceptable rigidity characteristics.

The FAA does not concur with the commenter's request. While the FAA accepts in principle that the Type II cargo pallets could be manufactured with acceptable rigidity characteristics, the commenter has not submitted any data or configuration definition that would allow their use. However, the commenter may request approval for an alternative method of compliance in accordance with the provisions of paragraph (c) of this AD. The request should include sufficient information for the FAA to evaluate the proposal. No change to the rule is necessary.

#### Request for Use of a Tether Assembly

One commenter requests that the proposed AD be revised to allow the use of a tether assembly. The commenter states that a tether assembly is a device that restricts the shifting of Type II cargo pallets such that the cargo shift will not affect the airplane's center of gravity. The commenter states that such an assembly appears to be an economical method to allow continued operation of the Model 757-200PF series airplane with Type II cargo pallets. However, another commenter states that it has evaluated such a system and concludes that, if used improperly, it could result in considerable damage to aircraft structure and cargo handling system components.

The FAA does not concur with the first commenter's request to allow the use of a tether assembly. While the FAA accepts in principle that a tether assembly should adequately address the identified unsafe condition, the FAA has concluded that it would be prudent to defer a decision until further information becomes available. The 28-month compliance time should allow sufficient time to resolve the issues raised by the second commenter prior to implementation of the W&B Manual revision. Assuming satisfactory resolution, the first commenter may request approval for an alternative method of compliance in accordance with the provisions of paragraph (c) of this AD. No change to the rule is necessary.

#### Explanation of Changes Made to Proposal

The FAA has revised paragraph (c) of the final rule to include instructions to submit requests of approval for an alternative method of compliance through an appropriate Principal Maintenance Inspector. The proposed rule only contained instructions to submit requests through an appropriate Principal Operations Inspector.

Operators should submit requests for approval for an alternative method of compliance for paragraph (a) of this AD through their Principal Operations Inspector, whereas requests for approval for an alternative method of compliance for paragraph (b) of this AD should be submitted through their Principal Maintenance Inspector.

#### Conclusion

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

#### Cost Impact

There are approximately 100 airplanes of the affected design in the worldwide fleet. The FAA estimates that 90 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required Airplane W&B Manual revision, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$5,400, or \$60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

#### Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is

contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**99-22-02 Boeing:** Amendment 39-11380. Docket 98-NM-338-AD.

**Applicability:** All Model 757-200PF series airplanes, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent inadvertent movement of a cargo pallet during flight, which could result in an adverse center of gravity condition and consequent reduced controllability of the airplane, accomplish the following:

#### Manual Revision

(a) Within 28 months after the effective date of this AD: Revise the Limitations Section of the FAA-approved Airplane Weight & Balance (W&B) Manual to include the following statement. This action may be accomplished by inserting a copy of this AD into the W&B Manual.

“Operation of any airplane without side vertical restraints installed on the main cargo deck when carrying any Type II cargo pallet is prohibited.”

#### Optional Corrective Action

(b) Installation of side vertical restraints in accordance with a method approved by the

Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate, constitutes terminating action for the requirements of paragraph (a) of this AD.

### Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector or Principal Maintenance Inspector, as applicable, who may add comments and then send it to the Manager, Seattle ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

### Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on November 24, 1999.

Issued in Renton, Washington, on October 13, 1999.

**D.L. Riggins,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 99-27272 Filed 10-19-99; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 99-NM-225-AD; Amendment 39-11379; AD 99-21-33]

**RIN 2120-AA64**

### Airworthiness Directives; Fokker Model F.27 Mark 050 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F.27 Mark 050 series airplanes. This action requires a one-time inspection to detect improper installation of countersunk screws used to attach the access panels to the bottom skin of the center wing; and corrective action, if necessary. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified in this AD are intended to detect and correct such improper installation, which could result in

fatigue cracking of the bottom skin of the center wing and consequent reduced structural integrity of the airplane.

**DATES:** Effective November 4, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 4, 1999.

Comments for inclusion in the Rules Docket must be received on or before November 19, 1999.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 99-NM-225-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, The Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

**SUPPLEMENTARY INFORMATION:** The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, notified the FAA that an unsafe condition may exist on certain Fokker Model F.27 Mark 050 series airplanes. The RLD advises that, on a number of airplanes on the production line, the heads of countersunk screws were found not to seat properly in their countersinkings. The affected screws are used in the attachment of access panels of the bottom skin of the center wing. This condition, if not corrected, could result in fatigue cracking of the bottom skin of the center wing and consequent reduced structural integrity of the airplane.

### Explanation of Relevant Service Information

Fokker has issued Service Bulletin SBF50-57-015, dated February 28, 1996, which describes procedures for a one-time detailed visual inspection to detect improper installation (excessive gap) of the countersunk screws in the access covers of the bottom skin of the center wing.

Fokker has also issued Service Bulletin SBF50-57-018, dated February 28, 1996, which describes procedures



for reaming of the fastener holes and an eddy current inspection to detect cracks in the bottom skin of the center wing. This service bulletin also describes procedures to repair any cracking that is found.

The RLD classified these service bulletins as mandatory and issued Dutch airworthiness directive 1996-042 (A), dated April 29, 1996, in order to assure the continued airworthiness of these airplanes in the Netherlands.

#### FAA's Conclusions

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

#### Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to detect and correct improper installation of countersunk screws in the attachment of access panels of the bottom skin of the center wing, which could result in fatigue cracking of the bottom skin and consequent reduced structural integrity of the airplane. This AD requires accomplishment of the actions specified in the service bulletins described previously.

#### Differences Between Rule and Service Bulletin

Operators should note that, although Fokker Service Bulletin SBF50-57-018 specifies that the manufacturer may be contacted for disposition of certain repair conditions, this AD would require the repair of those conditions to be accomplished in accordance with a method approved by the FAA.

#### Cost Impact

None of the airplanes affected by this action are on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is

necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 6 work hours to accomplish the required inspection, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this AD would be \$360 per airplane.

#### Determination of Rule's Effective Date

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, prior notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the **Federal Register**.

#### Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 99-NM-225-AD." The

postcard will be date stamped and returned to the commenter.

#### Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

##### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

##### 99-21-33 Fokker Services B.V.:

Amendment 39-11379. Docket 99-NM-225-AD.

**Applicability:** Model F.27 Mark 050 series airplanes, serial numbers 20103 through 20263 inclusive; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or



repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To detect and correct improper installation of countersunk screws in the attachment of access panels of the bottom skin of the center wing, which could result in fatigue cracking of the bottom skin of the center wing and consequent reduced structural integrity of the airplane, accomplish the following:

#### **Initial Inspection**

(a) Prior to the accumulation of 24,000 total flight cycles, perform a one-time detailed visual inspection to detect improper installation (excessive gap) of the countersunk screws used to attach the access panels to the bottom skin of the center wing, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF50-57-015, dated February 28, 1996.

**Note 2:** For the purposes of this AD, a detailed visual inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

#### **Inspection and Corrective Action**

(b) If any improper installation (excessive gap) is found during the inspection required by paragraph (a) of this AD: Prior to the accumulation of 24,000 total flight cycles, ream the fastener holes in the rabbet of the bottom skin of the center wing and perform an eddy current inspection for cracking of the fastener holes in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF50-57-018, dated February 28, 1996.

#### **Repair**

(1) For any fastener hole for which no crack is found during the eddy current inspection: Prior to further flight; accomplish corrective actions for the fastener hole, in accordance with Step C. of Repair Scheme No. 1 of Fokker Service Bulletin SBF50-57-018, dated February 28, 1996.

(2) For any fastener hole for which a crack is found during the eddy current inspection: Prior to further flight; repair and re-inspect the fastener hole, in accordance with Steps A. and B. of Repair Scheme No. 1 of Fokker Service Bulletin SBF50-57-018, dated February 28, 1996. For any crack that is outside the limits specified in the service bulletin, prior to further flight, repair in accordance with a method approved by either the Manager, International Branch,

ANM-116, FAA, Transport Airplane Directorate; or the Rijksluchtvaartdienst (RLD) (or its delegated agent). For a repair method to be approved by the Manager, International Branch, ANM-116, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

#### **Alternative Methods of Compliance**

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

#### **Special Flight Permits**

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

#### **Incorporation by Reference**

(e) Except as provided by paragraph (b)(2) of this AD, the actions shall be done in accordance with Fokker Service Bulletin SBF50-57-015, dated February 28, 1996, and Fokker Service Bulletin SBF50-57-018, dated February 28, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, The Netherlands. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 4:** The subject of this AD is addressed in Dutch airworthiness directive 1996-042 (A), dated April 29, 1996.

(f) This amendment becomes effective on November 4, 1999.

Issued in Renton, Washington, on October 8, 1999.

**D.L. Riggins,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 99-26933 Filed 10-19-99; 8:45 am]

**BILLING CODE 4910-13-P**

## **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

#### **14 CFR Part 39**

[Docket No. 98-NM-340-AD; Amendment 39-11378; AD 99-21-32]

**RIN 2120-AA64**

#### **Airworthiness Directives; McDonnell Douglas Model MD-90-30 Series Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model MD-90-30 series airplanes, that requires a one-time inspection to measure clearance and detect interference between the elevator cable pulley and the shroud frame of the ventral stairway, and modification of the shroud frame of the ventral stairway. This amendment is prompted by reports of pitch oscillation of several Model MD-90-30 series airplanes. The actions specified by this AD are intended to prevent interference between the elevator cable pulley and the shroud frame of the ventral stairway, which could result in pitch oscillation of the airplane, and consequent damage to the elevator cable pulley and reduced controllability of the airplane.

**DATES:** Effective November 24, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 24, 1999.

**ADDRESSES:** The service information referenced in this AD may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1-L51 (2-60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Jon Mowery, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960

Paramount Boulevard, Lakewood, California 90712-4137; telephone (562) 627-5322; fax (562) 627-5210.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD-90-30 series airplanes was published in the **Federal Register** on February 9, 1999 (64 FR 6259). That action proposed to require a one-time inspection to measure clearance and detect interference between the elevator cable pulley and the shroud frame of the ventral stairway, and modification of the shroud frame of the ventral stairway.

#### Comments

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

#### Support of the Proposal

Several commenters support the proposed rule.

#### Request to Shorten Compliance Time

One commenter requests that the proposed 12-month compliance time for accomplishment of the inspection specified in paragraph (a) of the proposed AD be shortened to 90 days. The commenter asserts that the proposed compliance time is too long in consideration of the flight critical nature of the unsafe condition. Based on the proposed compliance time, administrative procedure time to publish the final rule, and a possible "delayed" effective date, the commenter states that it could be 3 years or more before an operator must correct this unsafe condition, which is an unacceptable amount of time.

The FAA does not concur. In developing an appropriate compliance time, the FAA considered the safety implications, parts availability, and normal maintenance schedules for timely accomplishment of the inspection. Further, the proposed compliance time was arrived at with operator, manufacturer, and FAA concurrence. In consideration of all of these factors, the FAA determined that the compliance time, as proposed, represents an appropriate interval in which the inspection can be accomplished in a timely manner within the fleet and still maintain an adequate level of safety. Operators are always permitted to accomplish the requirements of an AD at a time earlier than that specified as the compliance time; therefore, if an operator elects to

accomplish the inspection prior to 12 months after the effective date of this AD, it is that operator's prerogative to do so. If additional data are presented that would justify a shorter compliance time, the FAA may consider further rulemaking on this issue.

#### Request to Shorten the Effective Date

One commenter requests that the maximum time from issuance to the effective date be no more than 30 days. The commenter suggests that the proposed compliance time may be unnecessarily extended by adding in the administrative procedures time to publish the final rule in the **Federal Register**.

The FAA does not concur with the commenter's request. The Administrative Procedure Act (APA) requires that Federal agencies provide at least 30 days after publication of a final rule in the **Federal Register** before making it effective, unless "good cause" can be found not to do so. Under the APA, the basis for this finding is similar to the basis for a finding of good cause to dispense with notice and comment procedures in issuing rules. In the case of certain AD's, the nature of the action may be of such urgency that for the FAA to take any additional time to provide notice and opportunity for prior public comment would be impracticable; in those cases, the FAA finds good cause for making the rule effective in less than 30 days. In the case of this AD action, however, the FAA did not consider that the addressed unsafe condition was of such a critical nature that time could not be afforded for notice and the opportunity for the public to comment on the rule. It follows then, that there is no basis for finding good cause for making this rule effective in less than 30 days. For domestic final rules following notice, the FAA assigns an effective date of 35 days after publication.

#### Explanation of Change Made to Proposal

The FAA has clarified the inspection requirement contained in the proposed AD. Whereas the proposal specified a visual inspection, the FAA has revised this final rule to clarify that its intent is to require a general visual inspection. Additionally, a note has been added to the final rule to define that inspection.

#### Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed with the change previously described. The FAA has determined that this change

will neither increase the economic burden on any operator nor increase the scope of the AD.

#### Cost Impact

There are approximately 58 airplanes of the affected design in the worldwide fleet. The FAA estimates that 58 airplanes of U.S. registry will be affected by this AD.

It will take approximately 1 work hour per airplane to accomplish the required inspection, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be \$3,480, or \$60 per airplane.

It will take approximately 2 work hours per airplane to accomplish the required modification, at an average labor rate of \$60 per work hour. Required parts will be provided by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the modification required by this AD on U.S. operators is estimated to be \$6,960, or \$120 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

#### Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

**List of Subjects in 14 CFR part 39**

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

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

**99-21-32 McDonnell Douglas:** Amendment 39-11378. Docket 98-NM-340-AD.

**Applicability:** Model MD-90-30 series airplanes, as listed in McDonnell Douglas Service Bulletin No. MD90-27-026, dated September 30, 1998; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent interference between the elevator cable pulley and the shroud frame of the ventral stairway, which could result in pitch oscillation of the airplane, and consequent damage to the elevator cable pulley and reduced controllability of the airplane, accomplish the following:

**Inspection**

(a) Within 12 months after the effective date of this AD, perform a one-time general visual inspection to measure clearance and detect interference between the elevator cable pulley and the shroud frame of the ventral stairway in accordance with Phase 1 of McDonnell Douglas Service Bulletin No. MD90-27-026, dated September 30, 1998.

**Note 2:** For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally

available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(1) If clearance is greater than or equal to 0.5 inch, and if no interference is detected: Within 18 months after performing the inspection, accomplish the requirements of paragraph (b) of this AD.

(2) If clearance is less than 0.5 inch, or if any interference is detected: Prior to further flight, accomplish the requirements of paragraph (b) of this AD.

**Modification**

(b) Modify the shroud frame of the ventral stairway in accordance with Phase 2 of McDonnell Douglas Service Bulletin No. MD90-27-026, dated September 30, 1998.

**Alternative Methods of Compliance**

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

**Special Flight Permits**

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

**Incorporation by Reference**

(e) The inspection and modification shall be done in accordance with McDonnell Douglas Service Bulletin No. MD90-27-026, dated September 30, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1-L51 (2-60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on November 24, 1999.

Issued in Renton, Washington, on October 8, 1999.

**D.L. Riggins,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 99-26934 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-13-U

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. 98-NM-244-AD; Amendment 39-11377; AD 99-21-31]

RIN 2120-AA64

**Airworthiness Directives; Saab Model SAAB SF340A and SAAB 340B Series Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain Saab Model SAAB SF340A and SAAB 340B series airplanes, that requires removing the control quadrant, securing the power lever cam screws with Loctite, and reinstalling the control quadrant. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent the cam screws of the engine power levers from backing out and interfering with the movement of the engine power levers, which could result in limited engine power, and consequent reduced controllability of the airplane.

**DATES:** Effective November 24, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 24, 1999.

**ADDRESSES:** The service information referenced in this AD may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S-581.88, Linköping, Sweden. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601

Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Saab Model SAAB SF340A and SAAB 340B series airplanes was published in the **Federal Register** on October 27, 1998 (63 FR 57260). That action proposed to require removing the control quadrant, securing the power lever cam screws with Loctite, and reinstalling the control quadrant.

#### Comments

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

#### Request To Withdraw Proposed AD

One commenter states that the proposed action (*i.e.*, removal of all control quadrants to put Loctite on the screws) is not warranted for the following reasons:

1. The proposed rule is based on two events that occurred at a single operator. Investigation of these events showed that the migrated screw was an incorrect part number from the flight idle stop assembly. The commenter notes that no other operators have reported this problem, which indicates that the installation was an error in the field, and not a problem introduced during the modification of the control quadrant by its vendor (Adams-Rite). The commenter also states that an audit of related inventory, kits, and items in stock at the control quadrant vendor found no screws with incorrect part numbers, which further indicates that the problem was caused by a field installation error of the flight idle stop modification kit.

2. The commenter states that a check of its spare throttle quadrants shows that the correct screws have been installed within the flight idle stop assembly and are installed tightly. There is no indication that these screws can migrate, or "back out" of place.

3. Given the amount of time and hours accrued since installation of the flight idle stop, the commenter states that any screws susceptible to such migration should already have shown signs of movement. The commenter further notes that a much simpler inspection would be to use a strong light and look through the power lever slot in the control quadrant to examine the screws, and only remove the quadrant if the screws show signs of looseness. An

inspection interval of 200 flight hours would be sufficient until the quadrant was removed for other causes, which would allow accomplishment of the service bulletin (*i.e.*, Saab Service Bulletin 340-76-042, dated May 28, 1998, including Attachments 1, 2, and 3, all dated May 1, 1998, was cited as the appropriate source of service information in this NPRM) at that time.

4. A test conducted at the control quadrant vendor showed that, in the worst-case, interference with the power levers caused by any migration of loose screws could be overcome by the flight crew using an additional 8 lbs of force. Therefore, the crew would not lose control of engine power.

The FAA does not concur with the commenter's statement that the proposed AD is not warranted. The FAA has determined that the actions required by this AD are appropriate for the reasons described below.

Although the commenter states that a single operator incorrectly installed the migrated screws, installation of any screws in the area affected by this AD would not have been accomplished by any operator, only by the vendor of the control quadrant.

Additionally, the FAA has been advised that the two control quadrants that have had the problem were manufactured in different batches with a long period of time in between.

The results of the audit at the control quadrant vendor do not adequately explain why incorrect screws were installed during manufacture of these two quadrants. Therefore, the FAA has determined that it is necessary to accomplish an inspection and modification of all quadrants.

The FAA also disagrees with the commenter's statement that it has determined that correct screws are installed inside its spare quadrants. Further discussions with Luftfartsverket (LFV), which is the airworthiness authority for Sweden, and Saab have revealed that it is not possible for operators to adequately check the installation of the correct screw length without disassembling the control quadrant. Further, such disassembly is only to be accomplished by the quadrant vendor.

The FAA also disagrees that the screws should already have migrated, or that they can be checked periodically for looseness. It may be possible for the screws to remain in place for some time due to friction below the head of the screw, and then suddenly become loose due to vibration. It is not possible to predict how quickly or when such an event would occur. A periodic inspection such as the commenter

suggests would not adequately prevent the possibility of a sudden restriction of power lever movement.

Although the FAA does not disagree with the results of the test showing that 8 lbs. of force would overcome restriction of the power levers, the FAA does not concur that such action on the part of the flight crew is appropriate. Since the flight crew would not be aware of the cause of the sudden binding in the power levers, they would not reasonably be expected to know what action to take, how much force to apply, and when to stop applying the extra force.

#### Request for Revision of Cost Impact Information

One commenter requests that the FAA remove the sentence that reads "required parts would be supplied by the manufacturer at no cost to the operators" from the Cost Impact section of the proposed AD. The commenter notes that no parts are necessary to accomplish the modification, only consumables (*i.e.*, Loctite and Loctite primer).

The FAA concurs with the commenter's request. The cost impact information, below, has been revised accordingly.

#### Conclusion

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

#### Cost Impact

The FAA estimates that 283 airplanes of U.S. registry will be affected by this AD, that it will take approximately 9 work hours per airplane to accomplish the required actions, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$152,820, or \$540 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

#### Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or

on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99-21-31 SAAB AIRCRAFT AB:

Amendment 39-11377. Docket 98-NM-244-AD.

Applicability: Model SAAB SF340A and SAAB 340B series airplanes, as listed in Saab Service Bulletin 340-76-042, dated May 28, 1998, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not

been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the cam screws of the engine power levers from backing out and interfering with the movement of the engine power levers, which could result in limited engine power, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 1,200 flight hours or 6 months after the effective date of this AD, whichever occurs first, remove the control quadrant, secure the power lever cam screws with Loctite, and reinstall the control quadrant, in accordance with Saab Service Bulletin 340-76-042, dated May 28, 1998, including Attachments 1, 2, and 3, all dated May 1, 1998.

(b) As of the effective date of this AD, no person shall install on any airplane any control quadrant unit having part number (P/N) 53082, 53162, or 53170, unless the control quadrant unit has been modified in accordance with this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The actions shall be done in accordance with Saab Service Bulletin 340-76-042, dated May 28, 1998, including Attachment 1, dated May 1, 1998, Attachment 2, dated May 1, 1998, and Attachment 3, dated May 1, 1998, which contains the following list of effective pages:

Page Nos.	Revision level shown on page	Date shown on page
1-4 .....	Original .....	May 28, 1998.
<b>Attachment 1</b>		
1-4 .....	Original .....	May 1, 1998.
<b>Attachment 2</b>		
1-4 .....	Original .....	May 1, 1998.
<b>Attachment 3</b>		
1-4 .....	Original .....	May 1, 1998.

This incorporation by reference was approved by the Director of the Federal

Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S-581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Swedish airworthiness directive 1-128, dated May 29, 1998.

(f) This amendment becomes effective on November 24, 1999.

Issued in Renton, Washington, on October 8, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.  
[FR Doc. 99-26935 Filed 10-19-99; 8:45 am]  
BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99-ACE-38]

Amendment to Class E Airspace; Lyons, KS

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Lyons, KS.

DATES: The direct final rule published at 64 FR 44398 is effective on 0901 UTC, November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426-3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the Federal Register on August 16, 1999 (64 FR 44398). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on November 4, 1999. No adverse

comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on October 1, 1999.

**Richard L. Day**

*Acting Manager, Air Traffic Division, Central Region.*

[FR Doc. 99-27286 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Airspace Docket No. 99-ACE-37]

#### Amendment to Class E Airspace; Ava, MO

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** This document confirms the effective date of a direct final rule which revises Class E airspace at Ava, MO.

**DATES:** The direct final rule published at 64 FR 44397 is effective on 0901 UTC, November 4, 1999.

**FOR FURTHER INFORMATION CONTACT:** Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426-3408.

**SUPPLEMENTARY INFORMATION:** The FAA published this direct final rule with a request for comments in the **Federal Register** on August 16, 1999 (64 FR 44397). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on November 4, 1999. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on October 1, 1999.

**Richard L. Day**

*Acting Manager, Air Traffic Division, Central Region.*

[FR Doc. 99-27287 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-13-M

## OFFICE OF THE TRADE REPRESENTATIVE

### 15 CFR Part 2014

#### Implementation of the Temporary Tariff-Rate Quota for Imports of Lamb Meat

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Interim rule with request for comments.

**SUMMARY:** This rule provides for the establishment of an export certificate procedure to assist in the orderly marketing of lamb meat imports from countries provided a specific import allocation under the temporary tariff-rate quota that the President has imposed on those products.

**DATES:** Interim rule effective on October 20, 1999. Comments must be received on or before December 20, 1999.

**ADDRESSES:** Comments may be sent to Teresa Howes, Director for Asian Agricultural Affairs, Office of the United States Trade Representative, 600 17th Street NW, Washington, DC 20506.

**FOR FURTHER INFORMATION CONTACT:** Teresa Howes, Director for Asian Agricultural Affairs, Office of the United States Trade Representative, 600 17th Street, NW, Washington, DC 20508; telephone: (202) 395-6127.

**SUPPLEMENTARY INFORMATION:** On July 7, 1999, the President issued Proclamation 7208 (64 FR 37387) (July 9, 1999), which established a temporary tariff-rate quota ("TRQ") and increased duties, effective July 22, 1999, on lamb meat imports to facilitate the domestic industry's adjustment to import competition. In order to provide for the efficient and fair administration of the TRQ, on July 30, 1999, the President issued Proclamation 7214 (64 FR 42265) (Aug. 4, 1999), which delegated to the United States Trade Representative ("USTR") authority to administer the TRQ.

To provide for the efficient and fair administration of the TRQ, USTR is establishing a procedure under which countries that have been allotted an in-quota allocation under the TRQ may use a system of export certificates to ensure that only those of its lamb meat exports specifically designated for the United States market are counted against the country's in-quota allocation.

Under the interim rule, a country that was provided a specific in-quota allocation under the TRQ may elect to have the United States Customs Service ("U.S. Customs") determine which lamb meat imports are to be counted against the country's in-quota allocation, and

thus be assessed the lower rate of duty applicable to in-quota imports, based on whether the country has issued (or authorized issuance of) an export certificate for that lamb meat. Two countries, Australia and New Zealand, were provided specific in-quota allocations under the TRQ. Both governments have requested USTR to establish an export certificate procedure to assist in the orderly marketing of their lamb meat exports to the United States while the TRQ is in effect.

A country wishing to avail itself of the export certificate procedure must notify USTR, and provide the necessary supporting information. Australia and New Zealand have provided the requisite supporting information, and USTR hereby determines that both countries are "participating countries" under the export certificate procedure. USTR intends to publish a notice in the **Federal Register** if Australia or New Zealand ceases to be a participating country.

U.S. Customs will ensure that no imports of lamb meat from a participating country are counted against the participating country's in-quota allocation unless the importer declares that there is a valid export certificate for that lamb meat. In the absence of such a declaration, such imports will be not be eligible for the in-quota rate of duty.

U.S. Customs will separately issue regulations governing its implementation of this rule.

#### Comments

Before adopting this interim regulation as a final rule, consideration will be given to any written comments that are timely submitted to USTR. Each person submitting a comment should include his or her name and address, and give reasons for any recommendation. After the comment period closes, USTR will publish in the **Federal Register** a final rule on this subject, together with a discussion of comments received and any amendments made to the interim rule as a result of the comments.

To simplify the processing and consideration of comments, commenters are encouraged to submit documents in electronic form accompanied by an original and one paper copy. All documents submitted in electronic form should be on DOS formatted 3.5" diskettes, and should be prepared in either WordPerfect format or a format that the WordPerfect program can convert and import into WordPerfect.

## The Regulatory Flexibility Act and Executive Order 12866

Pursuant to the provisions of 5 U.S.C. 553 (a), public notice is inapplicable to this interim rule because it is within the foreign affairs function of the United States. Also, for the above reason, there is no need for a delayed effective date under 5 U.S.C. 553(d). No regulatory flexibility analysis is required for this rule since neither 5 U.S.C. 553 nor any other provision of law requires publication of a general notice of proposed rulemaking with respect to this rule. Because no notice of proposed rulemaking is required for interim regulations, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply; and because this document involves a foreign affairs function of the United States and implements an international agreement, it is not subject to the provisions of E.O. 12866.

## List of Subjects in 15 CFR Part 2014

Export certificates, Imports, Lamb meat, Tariff-rate quotas.

For the reasons set out in the "Supplementary Information" section of this notice, 15 CFR is amended by adding the following new part 2014 to read as follows:

## PART 2014—IMPLEMENTATION OF TARIFF-RATE QUOTA FOR IMPORTS OF LAMB MEAT

- Sec.  
2014.1 Purpose.  
2014.2 Definitions.  
2014.3 Export certificates.

**Authority:** Proclamation Numbers 7208 and 7214; 19 U.S.C. 2253 (g)

### § 2014.1 Purpose.

The purpose of this part is to provide for the implementation of the tariff-rate quota for imports of lamb meat established in Proclamation 7208 (64 FR 37397) (July 9, 1999) and modified in Proclamation 7214 (64 FR 42265) (Aug. 4, 1999). In particular, this part provides for the administration of export certificates where a country that has an allocation of the in-quota quantity under the tariff-rate quota has chosen to use export certificates.

### § 2014.2 Definitions.

Unless the context otherwise requires, for the purpose of this subpart, the following terms shall have the meanings assigned below.

(a) *Lamb meat* means fresh, chilled, or frozen lamb meat, provided for in subheadings 0204.10.00, 0204.22.20, 0204.23.20, 0204.30.00, 0204.42.20, and 0204.43.20 of the HTS.

(b) *In-quota lamb meat* means lamb meat that is entered under the in-quota rate of duty.

(c) *Participating country* means any country to which an allocation of a particular quantity of lamb meat has been assigned under Proclamation 7208 that USTR has determined is, and has notified to the United States Customs Service as being, eligible to use export certificates.

(d) *Enter or Entered* means to enter or withdraw from warehouse for consumption.

(e) *HTS* means the Harmonized Tariff Schedule of the United States.

(f) *USTR* means the United States Trade Representative or the designee of the United States Trade Representative.

### § 2014.3 Export certificates.

(a) In-quota lamb meat may only be entered as a product of a participating country if the United States importer makes a declaration to the United States Customs Service, in the form and manner determined by the United States Customs Service, that a valid export certificate is in effect with respect to that lamb meat product.

(b) To be valid, an export certificate shall:

(1) Be issued by or under the supervision of the government of the participating country;

(2) Specify the name of the exporter, the product description and quantity, and the calendar year for which the export certificate is in effect;

(3) Be distinct and uniquely identifiable; and

(4) Be used in the calendar year for which it is in effect.

**Robert T. Novick,**  
*General Counsel, Office of the United States Trade Representative.*

[FR Doc. 99-27426 Filed 10-18-99; 8:45 am]

BILLING CODE 3190-01-P

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Parts 232, 239, 249, 259, 269 and 274

[Release Nos. 33-7752; 34-41986; 35-27081; 39-2376; IC-24075]

RIN 3235-AG96

### Adoption of Updated EDGAR Filer Manual

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is adopting an updated edition of the EDGAR Filer

Manual and is providing for its incorporation by reference into the Code of Federal Regulations. The Commission is also amending Form ID, the Uniform Application for Access Codes to File on EDGAR.

**EFFECTIVE DATE:** October 18, 1999. The new edition of the EDGAR Filer Manual (Release 6.6) will be effective on October 18, 1999. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of October 18, 1999.

**FOR FURTHER INFORMATION CONTACT:** In the Office of Information Technology, Michael E. Bartell at (202) 942-8800; for questions concerning investment company filings, Ruth Armfield Sanders, Senior Special Counsel, Division of Investment Management, at (202) 942-0978; and for questions concerning Corporation Finance company filings, Herbert Scholl at (202) 942-2930.

**SUPPLEMENTARY INFORMATION:** Today we are adopting an updated EDGAR Filer Manual ("Filer Manual"), which describes the technical formatting requirements for the preparation and submission of electronic filings through the Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system.<sup>1</sup> Filers must comply with the provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.<sup>2</sup> Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.<sup>3</sup>

The purpose of this new version of EDGAR and the Filer Manual (Release 6.6) is to incorporate changes resulting

<sup>1</sup> We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33-6986 (Apr. 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on June 28, 1999. See Release No. 33-7685 (May 17, 1999) [64 FR 27897].

<sup>2</sup> See Rule 301 of Regulation S-T (17 CFR 232.301).

<sup>3</sup> See Release Nos. 33-6977 (Feb. 23, 1993) [58 FR 14628], IC-19284 (Feb. 23, 1993) [58 FR 14848], 35-25746 (Feb. 23, 1993) [58 FR 14999], and 33-6980 (Feb. 23, 1993) [58 FR 15009] in which we comprehensively discuss the rules we adopted to govern mandated electronic filing. See also Release No. 33-7122 (Dec. 19, 1994) [59 FR 67752], in which we made the EDGAR rules final and applicable to all domestic registrants; Release No. 33-7427 (July 1, 1997) [62 FR 36450], in which we adopted minor amendments to the EDGAR rules; Release No. 33-7472 (Oct. 24, 1997) [62 FR 58647], in which we announced that, as of January 1, 1998, we would not accept in paper filings that we require filers to submit electronically; Release No. 34-40935 (Jan. 12, 1999) [64 FR 2843], in which we made mandatory the electronic filing of Form 13F; and Release No. 33-7684 (May 17, 1999) [64 FR 27888], in which we adopted amendments to implement the first stage of EDGAR modernization.



from the decision by CompuServe, a sub-contractor to TRW the developer of the EDGAR system, to discontinue its EDGAR services as of October 16, 1999. The changes in the Filer Manual are due to the change in the sub-contractor for the public data network for transmission of filings to EDGAR, private mailboxes for receiving EDGAR acceptance/suspension messages, and electronic return copies of filings. The EDGAR bulletin board and the EDGAR company database will no longer be available, but filers may obtain similar information from our Web Site at [www.sec.gov](http://www.sec.gov) and the TRW/UUNET Web Site at [www.trw-edgar.com](http://www.trw-edgar.com).

Filers who chose to use the TRW/UUNET services may sign up using the Web Site at [www.trw-edgar.com](http://www.trw-edgar.com) by filling out a questionnaire. TRW/UUNET will send new account information and a password. Filers who cannot access the web site can call 703-345-8900 for sign up information. The basic TRW/UUNET service will include five hours of access and a mailbox for messages. There will be additional charges for larger mailboxes and connect time over the basic limit. Those filers who want to use the public data network for transmission to EDGAR, who want a private system (instead of the Internet) for receipt of acceptance/suspense messages, or who want an electronic returned copy of their filings must sign up for this service. To access their new mailboxes, filers must use a standard POP3 mail client. Netscape Communicator, Microsoft Internet Explorer and several other Internet packages provide these clients. The [www.trw-edgar.com](http://www.trw-edgar.com) Web Site contains additional information.

We will install the new EDGAR private mail service on Saturday, October 16, 1999. We will begin delivering messages and return copies to the new mailboxes on Monday, October 18, 1999. We will also make the new public data network available for transmissions on Monday, October 18, 1999.

Due to the switch in private mail service, we are making several changes to the EDGAR system that deal with notification and the naming of certain tags. EDGAR will no longer support numeric private mail addresses (e.g., 75200,1024). The format for EDGAR private mail user IDs is 8 to 12 upper case alphabetical and numeric characters with an optional dash (-). We have renamed the tag <COMPUSERVE-ID>; the new name is <PRIVATE-MAIL-

ID>. We have revised the Filer Manual to reflect the changes described.<sup>4</sup>

We have revised Form ID,<sup>5</sup> the Uniform Application for Access Codes to File on EDGAR, to reflect the change in the EDGAR private mail service. We have also included an additional line in the Form ID for an optional Internet e-mail address.

We are amending Rule 301 of Regulation S-T to provide for the incorporation by reference of the Filer Manual into the Code of Federal Regulations, which incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The revised Filer Manual and the amendments to Rule 301 and to Form ID will be effective on October 18, 1999.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW, Washington DC 20549-0102. We will post electronic format copies on the SEC's Web Site. The SEC's Web Site address for the Filer Manual is <http://www.sec.gov/asec/ofis/filerman.htm>. You may also obtain copies from Disclosure Incorporated, the paper and microfiche contractor for the Commission, at (800) 638-8241.

Since the Filer Manual (including Form ID) relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).<sup>6</sup> It follows that the requirements of the Regulatory Flexibility Act<sup>7</sup> do not apply.

The effective date for the updated Filer Manual and the rule and form amendments is October 18, 1999. In accordance the APA,<sup>8</sup> we find that there is good cause to establish an effective date less than 30 days after publication of these rules and forms. The changes in the Filer Manual are due to the change in the sub-contractor for the public data network for transmission of filings to EDGAR, private mailboxes for receiving EDGAR acceptance/suspension messages, and electronic return copies of filings. If the changes do not become effective by October 18, it is likely that the ability of EDGAR users to make filings and send messages would be disrupted. This in turn could disrupt

securities offerings or the filing of timely public disclosures. In addition, we find there is good cause for the changes to the Form ID becoming effective in less than 30 days after publication because of the minor and technical nature of those changes.

### Statutory Basis

We are adopting the amendments to Regulation S-T and Form ID under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,<sup>9</sup> Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,<sup>10</sup> Section 20 of the Public Utility Holding Company Act of 1935,<sup>11</sup> Section 319 of the Trust Indenture Act of 1939,<sup>12</sup> and Sections 8, 30, 31, and 38 of the Investment Company Act.<sup>13</sup>

### List of Subjects

#### 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

#### 17 CFR Parts 239, 249, 259, 269 and 274

Reporting and recordkeeping requirements, Securities.

### Text of the Amendment

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

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

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

**Authority:** 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll(d), 79t(a), 80a-8, 80a-29, 80a-30 and 80a-37.

2. Section 232.301 is revised to read as follows:

#### § 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The October 1999 edition of the *EDGAR Filer Manual: Guide for Electronic Filing with the U.S. Securities and Exchange Commission (Release 6.6)* is incorporated by reference into the Code of Federal Regulations, which action

<sup>4</sup> In addition, we have revised Appendix C of the Filer Manual to update the pages entitled, "Examples of Document Header Tag Values for Investment Company Exhibits," and we have added examples of header tags for Form N-SAR exhibits.

<sup>5</sup> 17 CFR 239.63, 249.446, 259.602, 269.7 and 274.402.

<sup>6</sup> 5 U.S.C. 553(b).

<sup>7</sup> 5 U.S.C. 601-612.

<sup>8</sup> 5 U.S.C. 553(d)(3).

<sup>9</sup> 15 U.S.C. 77f, 77g, 77h, 77j and 77s(a).

<sup>10</sup> 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w and 78ll.

<sup>11</sup> 15 U.S.C. 79t.

<sup>12</sup> 15 U.S.C. 77sss.

<sup>13</sup> 15 U.S.C. 80a-8, 80a-29, 80a-30 and 80a-37.



was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549-0102 or by calling Disclosure Incorporated at (800) 638-8241. Electronic format copies are available on the SEC's Web Site. The SEC's Web Site address for the Manual is <http://www.sec.gov/asec/ofis/filerman.htm>. Information on becoming an EDGAR e-mail/electronic bulletin board subscriber is available by contacting TRW/UUNET at (703) 345-8900 or at [www.trw-edgar.com](http://www.trw-edgar.com).

### PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

3. The authority citation for Part 239 continues to read in part as follows:

**Authority:** 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78ll(d), unless otherwise noted.

### PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

4. The authority citation for Part 249 continues to read in part as follows:

**Authority:** 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78ll(d), unless otherwise noted.

### PART 259—FORMS PRESCRIBED UNDER THE PUBLIC UTILITY HOLDING ACT OF 1935

5. The authority citation for Part 259 continues to read in part as follows:

**Authority:** 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78ll(d), unless otherwise noted.

### PART 269—FORMS PRESCRIBED UNDER THE TRUST INDENTURE ACT OF 1939

6. The authority citation for Part 269 continues to read in part as follows:

**Authority:** 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78ll(d), unless otherwise noted.

### PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

7. The authority citation for Part 274 continues to read in part as follows:

**Authority:** 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, 78ll(d), unless otherwise noted.

8. By revising Form ID (referenced in §§ 239.63, 249.446, 259.602, 269.7 and 274.402 of this chapter) to read as follows:

**Note**—The text of Form ID does not appear in the Code of Federal Regulations.

#### OMB APPROVAL

OMB Number: 325-0328

Expires: May 31, 2001

Estimated average burden hours per response: 0.15

United States Securities and Exchange Commission,

Washington, DC 20549

Applicant's CIK (if known)

Form ID—Uniform Application for Access Codes To File on Edgar

☐ Initial application ☐ Amendment

Part I—Application for Access Codes To File on Edgar

Name of applicant (registrant's name as specified in its charter; individual's name for signature purposes; company or individual name of filing agent or training agent).

Former name (if changed since last application)

Mailing address or post office box no.:

City State Zip

Telephone number: ( )

E-Mail Address:

Applicant is a (see definitions in the General Instructions):

☐ Filer ☐ Filing agent ☐

Training agent

☐ Initial application for EDGAR access codes.

☐ Amended application for (see definitions in the General Instructions):

☐ CCC ☐ Password ☐ PMAC

☐ Amended application to change reported information only (access codes to remain the same)

Part II—Filer Information (to be completed by filers only)

If you currently file with the SEC, check this box ☐ and provide at least one of your SEC file numbers, if known:

1933 Act No.

2—

33—

333—

1934 Act No.

0—

1—

28—

1935 Act No.

70—

69—

1940 Act No.

811—

814—

Other No.

—

—

Registrant's tax number or federal identification number

Telephone number (include area code)

Primary business address or post office box no. (if different from mailing address)

City State Zip

State of incorporation/organization  
Fiscal year end (mm/dd)

Part III—Contact Information (to be completed by all applicants)

Person to receive EDGAR information, inquiries and access codes

Telephone number (include area code): ( )

Mailing address or post office box no. (if different from applicant's mailing address)

City State Zip

E-Mail Address:

If you are an EDGAR Private Mail subscriber, provide your User ID:

Part IV—Account Information (to be completed by filers and filing agents only)

Person to receive SEC account information and billing invoices

Telephone number (include area code) ( )

Mailing address or post office box no. (if different from applicant's mailing address)

City State Zip

Part V—Signature (to be completed by all applicants)

Signature: Type or print name:

Position or title: Date:

Section 19 of the Securities Act of 1933 (15 U.S.C. 77s), sections 13(a) and 23 of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) and 78w), section 319 of the Trust Indenture Act of 1939 (15 U.S.C. 77sss), section 20 of the Public Utility Holding Company Act of 1935 (15 U.S.C. 79t) and sections 30 and 38 of the Investment Company Act of 1940 (15 U.S.C. 80a-29 and 30a-37) authorize solicitation of this information. We will use this information to assign system identification to filers, filing agents, and training agents. This will allow the Commission to identify persons sending electronic submissions and grant secure access to the EDGAR system.

SEC (x/xx) Persons who potentially are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

#### Form ID—General Instructions

##### Using and Preparing Form ID

Use Form ID to apply for or to amend the following EDGAR codes:

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**CIK Confirmation Code (CCC)**—You will use the CCC in the header of your filings in conjunction with your CIK to ensure that you authorized the filing

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Please see the EDGAR Filer Manual for instructions on how to file electronically, including how to use the access codes

You must complete all items in any parts which apply to you. If any item in any part does not apply to you, please mark that part "NA." If your form is incomplete, it may take us longer to assign your access codes

**Part I—Applicant Information** (to be completed by all applicants)

Please check the appropriate box to indicate whether you will be sending electronic submissions as a filer, filing agent, or training agent. Mark only one of these boxes per application. A "filer" is any person or entity on whose behalf an electronic filing is made. A "filing agent" is a financial printer, law firm, or other party which will be using these access codes to send a filing or portion of a filing on behalf of a filer. A "training agent" is any person or entity which will be sending only test filings in conjunction with training other persons.

If you do not already have access codes, please mark the "Initial application" box, and complete all other items in Parts II through V that apply to you.

If you already have access codes, please provide your CIK in the upper left corner, and mark the boxes to indicate the reason you are filing the amendment and any access codes you want to replace. You also should complete Part V (signature) and those items in Parts II through IV which have changed from the previous application. You may change your access codes (except your PMAC) and most other information on Form ID electronically via EDGAR. See the EDGAR Filer Manual for details.

**Part II—Filer Information** (to be completed by filers only)

The registrant's tax or federal identification number is the number issued by the Internal Revenue Service. Foreign private issuers should include all zeroes if they do not have a tax or federal identification number. (We do not require this number for individuals.)

We do not require state of incorporation/organization or fiscal year end for individuals. We request that foreign private issuers include their country of organization.

**Part III—Contact Information** (to be completed by all applicants)

In this section, identify the individual who should receive the access codes and EDGAR-related information.

If you are or become an EDGAR Private Mail subscriber, you can receive acceptance and suspension messages and any requested return copies of your filings via electronic mail at your expense. If you do not subscribe to EDGAR Private Mail, you can receive your acceptance and suspension messages via Internet E-Mail if you provide an address. We will not send return copies of filings to an Internet address.

**Part IV—Account Information** (to be completed by filers and filing agents only)

Identify in this section the individual who should receive account information and/or billing invoices from us. We will use this information to electronically process fee payments and billings.

**Part V—Signature** (to be completed by all applicants)

Send your manually signed and dated form to: Branch of Filer Support, U.S. Securities and Exchange Commission, Operations Center, Stop 0-7, 6432 General Green Way, Alexandria, VA 22312.

Dated: October 7, 1999.

By the Commission.

**Margaret H. McFarland,**  
*Deputy Secretary.*

[FR Doc. 99-26985 Filed 10-19-99; 8:45 am]

**BILLING CODE 8010-01-P**

## DEPARTMENT OF THE TREASURY

### Customs Service

#### 19 CFR Parts 24, 159 and 174

[T.D. 99-75]

RIN 1515-AB76

#### Interest on Underpayments and Overpayments of Customs Duties, Taxes, Fees and Interest

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** Interim rule.

**SUMMARY:** This document conforms the Customs Regulations to existing statutory provisions and judicial precedent regarding the assessment of interest due to underpayments or overpayments to Customs of duties, taxes and fees pertaining to imported merchandise, including interest thereon. The majority of the conforming changes reflect the terms of section 505 of the Tariff Act of 1930 (19 U.S.C. 1505), as amended by section 642(a) within the

Customs Modernization provisions of the North American Free Trade Agreement Implementation Act. Under that statute, interest accrues initially from the date the duties, taxes, fees and interest are deposited with Customs in the case of overpayments, or are required to be deposited with Customs in the case of underpayments, but in either case not beyond the date of liquidation or reliquidation of the applicable entry or reconciliation. Also under the statute and applicable judicial precedent, all bills issued by Customs for underpayments of duties, taxes, fees and interest are due within 15 or 30 days of issuance. In addition, the document conforms the Customs Regulations to other changes to 19 U.S.C. 1505 and to section 321 of the Tariff Act of 1930 (19 U.S.C. 1321) regarding interest that were made by sections 2(a) and 3(a)(12) of the Miscellaneous Trade and Technical Corrections Act of 1996.

**DATES:** Interim rule effective October 20, 1999. Comments must be received on or before December 20, 1999.

**ADDRESSES:** Written comments (preferably in triplicate) may be addressed to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service 1300 Pennsylvania Avenue, N.W., 3rd Floor, Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:** Robert Reiley, Financial Management Division (202-927-1504).

#### SUPPLEMENTARY INFORMATION:

##### Background

##### *Present Regulatory Provisions*

The regulatory provisions amended by this document are as follows:

Section 24.1 of the Customs Regulations (19 CFR 24.1) sets forth general procedures governing the collection of "Customs duties, taxes, and other charges," including the permissible methods of payment.

Section 24.3 of the Customs Regulations (19 CFR 24.3) sets forth general provisions regarding the rendering and payment of bills or accounts for money due the United States and the issuance of receipts therefor. Paragraph (e) of that section provides that (1) a bill for increased or additional duties determined to be due upon a liquidation or reliquidation is due 15 days from the date of such liquidation or reliquidation and (2) all other bills are due and payable upon the bill date appearing on the bill.

Section 24.3a of the Customs Regulations (19 CFR 24.3a) contains detailed provisions regarding Customs bills for supplemental duties (increased or additional duties assessed upon liquidation or reliquidation), reimbursable services, and miscellaneous amounts (bills other than duties, taxes, reimbursable services, liquidated damages, fines, and penalties), including interest thereon.

Section 24.11 of the Customs Regulations (19 CFR 24.11) concerns the issuance of bills for "increased or additional duties or taxes found due upon liquidation" and provides for issuance of such bills to the importer of record or, in certain circumstances, to the actual owner.

Section 24.25 of the Customs Regulations (19 CFR 24.25) concerns statement processing and automated clearinghouse filing and payment procedures and, in the second sentence of paragraph (a), refers to a single payment of "duties, taxes and fees."

Section 24.36 of the Customs Regulations (19 CFR 24.36) concerns refunds of excessive duties or taxes, and paragraph (a) thereof specifically provides for preparation of a refund "[w]hen it is found on liquidation or reliquidation of an entry that a refund of excessive duties or taxes, or both, is due."

Section 159.6 of the Customs Regulations (19 CFR 159.6) concerns the treatment by Customs of differences of less than \$20 and \$20 or more, between estimated deposits and amounts assessed on liquidation. This section specifically refers in these contexts to "duties, fees, and taxes" or to "duties and fees and internal revenue taxes."

Section 174.11 of the Customs Regulations (19 CFR 174.11) sets forth the matters that may be the subject of an administrative protest. Paragraph (c) of that section specifically refers to "charges or exactions" of whatever character within the jurisdiction of the Secretary of the Treasury.

Section 174.12 of the Customs Regulations (19 CFR 174.12) sets forth the procedures for filing a protest. Paragraph (a)(2) of that section provides that a protest may be filed by any person "paying any charge or exaction."

#### *Customs Modernization Statutory Changes*

The Customs Modernization provisions contained in Title VI of the North American Free Trade Agreement Implementation Act ("the Act"), Public Law 103-182, 107 Stat. 2057, included, in section 642(a), an extensive amendment of section 505 of the Tariff Act of 1930 (19 U.S.C. 1505). Prior to

this amendment, section 505 consisted of three subsections covering the deposit of estimated duties (subsection (a)), the collection of increased or additional duties and the refund of excess duties deposited as determined on a liquidation or reliquidation (subsection (b)), and the due date for duties determined to be due upon liquidation or reliquidation, delinquency, and interest on delinquent duty payments (subsection (c)). Section 505, as amended by section 642(a) of the Act, now contains the following provisions:

1. Subsection (a) of amended section 505 requires the importer of record to deposit with Customs, at the time of making entry or at such later time as the Secretary of the Treasury may prescribe by regulation, the amount of duties "and fees" estimated to be payable on the entry. In addition, subsection (a) now provides (1) that the regulations prescribed by the Secretary may provide that estimated duties and fees shall be deposited before or at the time an import activity summary statement is filed and (2) that if an import activity summary statement is filed, the estimated duties and fees shall be deposited together with interest, at a rate determined by the Secretary of the Treasury, accruing from the first date of the month the statement is required to be filed until the date such statement is actually filed. (An import activity summary statement is a filing procedure provided for in section 484 of the Tariff Act of 1930, as amended [19 U.S.C. 1484], and was added by section 637(a) of the Act to permit the filing of a single statement, covering entry or warehouse withdrawal transactions made during a calendar month, within such time period as prescribed by the Secretary of the Treasury by regulation but not later than the 20th day following such calendar month. Implementation of the import activity summary statement procedure will be the subject of a separate regulatory action and thus is not dealt with in this document.) Thus, in order to avoid a potential conflict with the import activity summary statement procedure, subsection (a), as amended, no longer contains a 30-day limitation on the authority of the Secretary of the Treasury to prescribe by regulation for the deposit of estimated duties after the date of entry.

2. Subsection (b) of amended section 505 requires Customs to collect any increased or additional duties "and fees due, together with interest thereon," and to "refund any excess moneys deposited, together with interest thereon," as determined on a liquidation or reliquidation. In addition,

subsection (b) now provides (1) that duties, fees, and interest determined to be due upon liquidation or reliquidation are due 30 days after issuance of the bill for payment and (2) that refunds of excess moneys deposited, together with interest thereon, shall be paid within 30 days of liquidation or reliquidation. Thus, in addition to the inclusion of new references to the collection of fees and interest, to the refund of excess "moneys" (which would include fees) and interest thereon, and to a due date based on the issuance of a bill, section 505, as amended, prescribes a specific time limit for the payment of refunds and no longer provides that duties determined to be due upon liquidation or reliquidation shall be due 15 days after the date of that liquidation or reliquidation (see also the discussion of subsection (d) below).

3. Subsection (c) of amended section 505 is essentially new and provides (1) that interest assessed due to an underpayment of duties, fees, or interest shall accrue, at a rate determined by the Secretary of the Treasury, from the date the importer of record is required to deposit estimated duties, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation and (2) that interest on excess moneys deposited shall accrue, at a rate determined by the Secretary of the Treasury, from the date the importer of record deposits estimated duties, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation. (Reconciliation is a procedure provided for in section 484 of the Tariff Act of 1930, as amended [19 U.S.C. 1484], and was added by section 637(a) of the Act to allow elements of an electronic entry summary or electronic import activity summary statement [other than those elements related to the admissibility of the merchandise], if undetermined at the time the summary or statement is filed, to be provided to Customs at a later time. Reconciliation will be implemented by separate regulatory action and thus is not substantively addressed in this document.) Thus, the importer of record is liable for interest on underpaid amounts from the date those amounts should have been paid to Customs, and, conversely, the importer of record is entitled to interest on refunds of payments made to Customs in excess of the amount properly due.

4. Finally, subsection (d) of amended section 505 provides (1) that if duties, fees, and interest determined to be due or refunded are not paid in full within the 30-day period specified in subsection (b), any unpaid balance shall be considered delinquent and bear

interest by 30-day periods, at a rate determined by the Secretary of the Treasury, from the date of liquidation or reliquidation until the full balance is paid and (2) that no interest shall accrue during the 30-day period in which payment is actually made. In addition, subsection (d) of amended section 505 reflects the terms of present § 24.3a(c)(3) of the regulations in that it provides for a 30-day period for payment both before and once a delinquency occurs, during which period no additional interest (that is, on any outstanding principal amount, plus interest thereon) will accrue so long as full payment of the amount outstanding is made during that current 30-day period. Thus, section 505 no longer allows for delinquency and interest accrual only after 45 days following liquidation or reliquidation. This is because the statutory delinquency period is now 30 days and because under the statute initial interest accrual on underpayments runs from the date of required deposit of moneys rather than only when a delinquency has occurred.

Customs has determined that the changes to section 505 effected by section 642(a) of the Act as described above require a number of conforming changes to the provisions of §§ 24.1, 24.3, 24.3a, 24.11, 24.25 and 24.36 of the regulations. These changes, which are explained in more detail below, concern principally the inclusion of references to the following: the collection or deposit of (estimated) fees and interest; the collection of increased or additional fees; the refund of excess fees deposited; the accrual of interest on underpaid and overpaid duties, fees and interest from the date of required (including actual) deposit to the date of liquidation or reliquidation and the collection or refund of such accrued interest; and the 30-day due date periods for payments or refunds of underpaid or overpaid duties, fees and interest as determined on liquidation or reliquidation. In addition, some of these regulatory provisions, as well as §§ 174.11 and 174.12 of the regulations, are in need of additional wording changes, involving principally the addition of references to "interest" or "taxes" or "refunds," in order to conform the regulatory texts to the principles reflected in applicable judicial decisions; these changes are also explained in more detail below.

#### *Additional Statutory Changes Regarding Interest*

Subsequent to the changes to section 505 effected by section 642(a) of the Act as discussed above, additional statutory changes regarding interest were enacted

as part of the Miscellaneous Trade and Technical Corrections Act of 1996 ("the Miscellaneous Act"), Public Law 104-295, 110 Stat. 3514. These statutory changes, which require conforming regulatory changes, were as follows:

1. Section 2(a) of the Miscellaneous Act amended section 505(c) to provide that, in the case of a claim under 19 U.S.C. 1520(d) (that is, a NAFTA post-importation claim for a refund of duty), interest on the excess money deposited shall accrue from the date on which the claim is made; under section 2(b) of the Miscellaneous Act, the section 2(a) amendment applies to claims made on or after June 7, 1996. Since this statutory amendment relates only to interest on excess deposits, Customs believes that it should be reflected in the § 24.36 refund provisions.

2. Section 3(a)(12) of the Miscellaneous Act amended section 321(a) of the Tariff Act of 1930 (19 U.S.C. 1321(a)) by the addition of several references to "interest." The addition of these references extends the authority of the Secretary of the Treasury to include interest in determining what is a *de minimis* amount when providing by regulation for waiving the collection of *de minimis* amounts on entered merchandise and for disregarding *de minimis* differences between the total estimated deposit or tentatively assessed amount and the total amount actually accruing on an entry of merchandise; under section 3(b) of the Miscellaneous Act, the section 3(a)(12) amendments apply as of December 8, 1993. Customs believes that the statutory amendment pertaining to the disregarding of differences between the total estimated deposit or tentatively assessed amount (that is, of duties, fees, and taxes) and the total amount (of duties, fees, taxes, and interest) actually accruing (which is normally determined upon liquidation of the entry) should be reflected in § 159.6 of the regulations which implements this aspect of the section 321(a) provisions.

#### **Explanation of Amendments**

The specific regulatory amendments set forth in this document are explained in more detail below.

##### *Section 24.1*

The amendments to § 24.1 involve the addition of references to "fees" and "interest" in various paragraphs under the section. This is simply intended to reflect the inclusion of these terms in the text of section 505 as amended by section 642(a) of the Act. Since § 24.1 sets forth general rules for collection (including payment method) of funds

due Customs and thus covers both initial payments and supplemental payments pursuant to a bill issued by Customs, the added "interest" references are intended to cover (1) any interest that may be initially due on estimated duties and fees under the import activity summary statement procedure mentioned above to be implemented later and (2) any interest assessed on underpayments and delinquent payments of principal amounts and interest thereon under § 24.3a. However, no reference to "interest" has been added in paragraph (a)(7) of § 24.1 because this paragraph concerns initial credit or charge card payments on non-commercial transactions, which would never involve an interest payment.

##### *Section 24.3*

The first sentence of § 24.3(b) is amended by adding references to the payment of estimated "fees" and "interest" in order to align the text on the terminology used in amended section 505. The words "if applicable" have been included after the added "interest" reference in recognition of the fact that interest would be required in an estimated payment circumstance only in some cases. A reference to the payment of estimated "taxes" has also been added to this regulatory text in order to reflect the fact that Customs collects taxes (e.g. harbor maintenance taxes) at the time of entry as part of the entry/liquidation process. Prior to the United States Supreme Court decision in *United States Shoe Corp. v. United States*, 118 S. Ct. 1290 (1998), Customs considered such harbor maintenance assessments to be "fees." However, the Supreme Court held that such assessments are "taxes." Since Customs continues to be required by law to collect such assessments and other taxes, the regulations are being amended to reflect accurately the fact that Customs collects taxes at entry.

In addition, the text of § 24.3(e) has been revised. The text revision involves the following changes: (1) in the first sentence, the addition of references to bills for "fees" and "interest" and the inclusion of a statement that bills are due and payable "within 30 days of the date of issuance of the bill"; (2) the elimination of the outdated second sentence (which provided that a bill for increased or additional duties is due 15 days from the date of liquidation or reliquidation); and (3) the inclusion of an exception for bills resulting from dishonored checks or from dishonored Automated Clearinghouse (ACH) transactions, for which the revised text prescribes a 15-day bill payment period

(see also the changes to § 24.3a regarding debit vouchers as discussed and set forth below). The last change reflects Customs' practice of requiring that bills for dishonored checks or dishonored ACH transactions be paid within 15 days of issuance of the bill. Interest assessments on such dishonored payments are provided for in the amendments to § 24.3a and are authorized because there is no statutory provision to the contrary. See *Billings v. United States*, 232 U.S. 261 (1914) and *United States v. Goodman*, 572 F. Supp. 1284 (CIT 1983).

#### Section 24.3a

In § 24.3a, the paragraph (a) discussion of supplemental duties has been modified to align on the terminology used in subsection (b) of amended section 505 and to reflect the considerations regarding taxes set forth above. Specifically, the words "taxes and fees" have been included after "duties" in two places, the words "increased or" have been included before "additional duties" within the parentheses, and the words "together with interest thereon," have been included after the parenthetical reference.

In addition, paragraph (b)(2) of § 24.3a has been revised to conform to the terms of amended section 505 regarding the accrual of interest on underpayments of duties, fees, and interest. In the revised text, paragraph (b)(2)(i), which concerns interest on initial underpayments and relates to subsection (c) of section 505, incorporates a number of illustrative examples and is further subdivided into subparagraphs (A), (B) and (C) in order to cover factual situations that arise under current Customs transaction practices and that of necessity will result in variations in the interest computation period under the basic statutory rule: subparagraph (A) concerns pre-liquidation excessive refunds; subparagraph (B) describes three scenarios involving pre-liquidation additional deposits; and subparagraph (C) concerns cases in which Customs receives a debit voucher indicating that a payment to Customs was not made because of a dishonored check or ACH transaction. Paragraph (b)(2)(ii) concerns interest on overdue bills and is based on subsection (d) of section 505.

#### Section 24.11

Section 24.11 has been modified by removing former paragraph (b) which affected only internal Customs procedures that are not appropriate for regulatory treatment. In addition, the remaining text (former paragraph (a))

has been simplified and references to increased or additional "fees" and "interest" have been inserted in the text and in the section heading.

#### Section 24.25

In § 24.25, the second sentence of paragraph (a) has been amended to reflect that interest may be due on a statement processing transaction.

#### Section 24.36

Section 24.36 is amended by revising the first sentence of paragraph (a), by adding a new sentence at the end of paragraph (a) followed by new paragraphs (a)(1)–(a)(3), by making wording changes in the first sentence of paragraph (b), and by making similar wording changes in paragraph (c). These changes reflect the amended section 505 provisions regarding the refund of excess moneys deposited and thus include the addition of references to the refund of excessive "fees" and "interest" and to the 30-day deadline for timely refunds, as provided for in section 505(b). Similar to the approach taken in § 24.3a(b)(2)(i) as discussed above, the modified § 24.36 text incorporates a number of illustrative examples and sets forth several scenarios, involving pre-liquidation additional excess deposits and pre-liquidation refunds, that arise in practice and require variations to the interest computation period under the basic statutory rule. The modified § 24.36 text also includes a specific reference to interest accrual in the case of a claim for a refund filed under 19 U.S.C. 1520(d) and Subpart D of Part 181 of the Customs Regulations; this change reflects the amendment to section 505(c) effected by section 2(a) of the Miscellaneous Act as discussed above. Finally, the changes incorporate the 30-day interest period provisions for delinquent refunds as provided for in section 505(d).

#### Section 159.6

A reference to "interest" has been added in each place where reference is made to duties, fees, and taxes assessed or found due in a liquidation or reliquidation context, to reflect the change to section 321(a) effected by section 3(a)(12) of the Miscellaneous Act as discussed above.

#### Sections 174.11 and 174.12

In § 174.11, a specific reference to the accrual of interest has been added in paragraph (c) to reflect that interest is a charge or exaction subject to protest within 90 days of the decision concerning such accrual. See *New Zealand Lamb Co. Inc. v. United States*,

40 F.3d 377 (Fed. Cir. 1994); *Syva Co. v. United States*, 681 F. Supp. 885 (CIT 1988); and *Travenol Laboratories Inc. v. United States*, 118 F.3d 749 (Fed. Cir. 1997). In addition, a reference to receiving a refund has been added in paragraph (a)(2) of § 174.12. These two changes clarify that both the assessment and the refund (or non-refund) of interest are protestable decisions.

#### Comments

Before adopting these interim regulations as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this interim rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on normal business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., 3rd Floor, Washington, D.C.

#### Inapplicability of Prior Public Notice and Comment Procedures and Delayed Effective Date Requirements

Pursuant to the provisions of 5 U.S.C. 553(b)(B), Customs has determined that prior public notice and comment procedures on these regulations are unnecessary and contrary to the public interest. The regulatory changes correct the Customs Regulations by conforming them to the terms of statutory provisions, and to the principles reflected in judicial decisions, that are currently in effect. In addition, in some cases, the changes conform the regulatory provisions to longstanding Customs administrative procedures and practices that confer benefits on, or otherwise militate in favor of, the general public. For the same reasons, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (3), Customs finds that there is good cause for dispensing with a delayed effective date.

#### Executive Order 12866

This document does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

#### Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for interim regulations, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

**List of Subjects****19 CFR Part 24**

Accounting, Claims, Customs duties and inspection, Interest, Taxes, User fees, Wages.

**19 CFR Part 159**

Computer technology, Customs duties and inspection, Entry, Imports, Liquidation.

**19 CFR Part 174**

Administrative practice and procedure, Customs duties and inspection, Protests.

**Amendments to the Regulations**

For the reasons stated in the preamble, Parts 24, 159 and 174 of the Customs Regulations (19 CFR Parts 24, 159 and 174) are amended as set forth below.

**PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE**

1–2. The general authority citation for Part 24 is revised, and the specific authority citation for § 24.24 is removed, and the specific authority citations for §§ 24.1, 24.11 and 24.36 continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1505, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 9701.

Section 24.1 also issued under 19 U.S.C. 197, 198, 1648;

\* \* \* \* \*

Section 24.11 also issued under 19 U.S.C. 1485(d);

\* \* \* \* \*

Section 24.36 also issued under 26 U.S.C. 6423.

**§ 24.1 [Amended]**

3. In § 24.1:

a. The section heading is amended by adding “fees, interest,” after “taxes,”;

b. The introductory text of paragraph (a) is amended by adding “fees, interest,” after “taxes,”;

c. The first sentence of paragraph (a)(3)(i) is amended by adding “fees, interest,” after “taxes,”;

d. The first sentence of paragraph (a)(7) is amended by adding “, fees,” after “taxes,”;

e. The first sentence of the introductory text of paragraph (b) is amended by adding “fees, interest,” after “taxes,”;

f. Paragraph (b)(3) is amended by adding “fees,” after “taxes,”;

g. Paragraph (d) is amended by adding “fees, interest,” after “taxes,”; and

h. In paragraph (e), the first sentence is amended by adding “, interest,” after “fees” and the second sentence is amended by adding “, fees, interest,” after “taxes”.

4. In § 24.3, the first sentence of paragraph (b) is amended by adding “, taxes, fees, and interest, if applicable,” after “duties” and paragraph (e) is revised to read as follows:

**§ 24.3 Bills and accounts; receipts.**

\* \* \* \* \*

(e) Except for bills resulting from dishonored checks or dishonored Automated Clearinghouse (ACH) transactions, all other bills for duties, taxes, fees, interest, or other charges are due and payable within 30 days of the

date of issuance of the bill. Bills resulting from dishonored checks or dishonored ACH transactions are due within 15 days of the date of issuance of the bill.

5. In § 24.3a:

a. The section heading is revised;

b. Paragraph (a) is amended by removing the words “Supplemental duties (additional duties assessed upon liquidation or reliquidation),” and adding, in their place, the words “supplemental duties, taxes and fees (increased or additional duties, taxes and fees assessed upon liquidation or reliquidation) together with interest thereon,”; and

c. Paragraph (b)(2) is revised.

The revisions read as follows:

**§ 24.3a Customs bills; interest assessment; delinquency; notice to principal and surety.**

\* \* \* \* \*

(b) \* \* \*

(2) *Interest on supplemental duties, taxes, fees, and interest*—(i) *Initial interest accrual.* Except as otherwise provided in paragraphs (b)(2)(i)(A) through (b)(2)(i)(C) of this section, interest assessed due to an underpayment of duties, taxes, fees, or interest shall accrue from the date the importer of record is required to deposit estimated duties, taxes, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

*Example: Entry underpaid as determined upon liquidation*

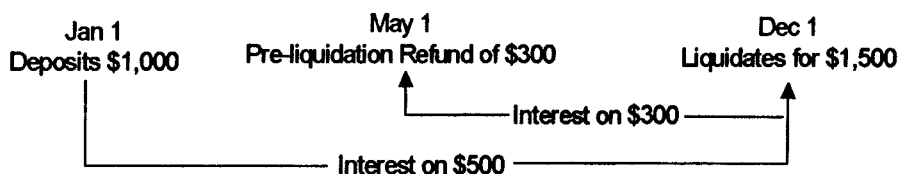


Importer owes \$500 plus interest as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$500 plus interest. The interest will accrue from the date payment was due (January 1) to date of liquidation (December 1).

(A) If a refund of duties, taxes, fees, or interest was made prior to liquidation or reliquidation and is determined upon liquidation or reliquidation to be excessive, in addition to any other interest accrued under this paragraph (b)(2)(i), interest also shall accrue on the

excess amount refunded from the date of the refund to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

*Example: Pre-liquidation refund but entry liquidates for an increase*



Importer owes \$800 plus interest as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and receives a pre-liquidation refund of \$300 (May 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$800 plus interest. The interest accrues in two segments: (1) On the original underpayment (\$500) from the date of deposit (January 1) to the date of liquidation (December 1); and (2) on the pre-liquidation

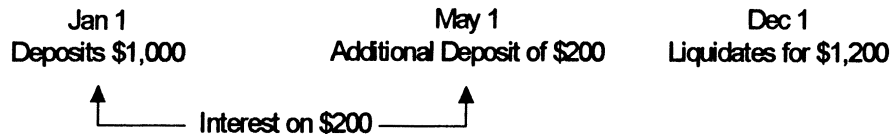
refund (\$300) from the date of the refund (May 1) to the date of liquidation (December 1).

(B) The following rules shall apply in the case of an additional deposit of duties, taxes, fees, or interest made prior to liquidation or reliquidation:

(1) If the additional deposit is determined upon liquidation or reliquidation of the applicable entry or

reconciliation to constitute the correct remaining balance that was required to be deposited on the date the deposit was due, interest shall accrue on the amount of the additional deposit only from the date of the initial deposit until the date the additional deposit was made. An example follows:

*Example: Additional deposit made and entry liquidates for total amount deposited*

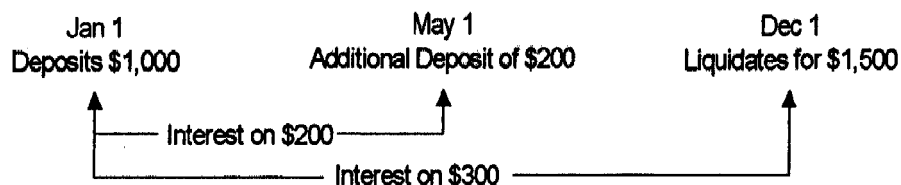


Importer owes interest on \$200 as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$1,200 (December 1). Upon liquidation, the importer will be billed for interest on the original \$200 underpayment from the date of the initial deposit (January 1) to the date of the additional deposit (May 1).

(2) If the additional deposit is determined upon liquidation or reliquidation of the applicable entry or reconciliation to be less than the full balance owed on the amount initially required to be deposited, in addition to any other interest accrued under this paragraph (b)(2)(i), interest also shall

accrue on the remaining unpaid balance from the date deposit was initially required to the date of liquidation or reliquidation. An example follows:

*Example: Additional deposit made and entry underpaid as determined upon liquidation*



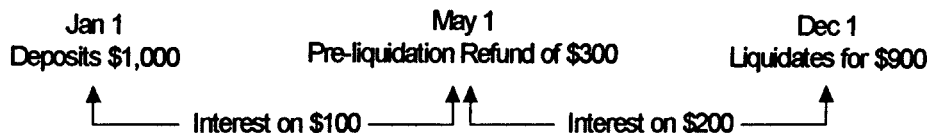
Importer owes \$300 plus interest as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$300 plus interest. The interest accrues in two segments: (1) on the additional deposit (\$200), from the date deposit was required (January 1) to the date

of the additional deposit (May 1); and (2) on the remaining underpayment (\$300), from the date deposit was required (January 1), to the date of liquidation (December 1).

(3) If an entry or reconciliation is determined upon liquidation or reliquidation to involve both an excess deposit and an excess refund made prior to liquidation or reliquidation, interest

in each case shall be computed separately and the resulting amounts shall be netted for purposes of determining the final amount of interest to be reflected in the underpaid amount. An example follows:

*Example: Excess pre-liquidation deposit and excess pre-liquidation refund*



Importer owes \$200 plus or minus net interest as follows:

The importer makes a \$1,000 initial deposit on the required date (January 1) and receives a pre-liquidation refund of \$300 (May 1) and the entry liquidates for \$900 (December 1). Upon liquidation, the importer will be billed for \$200 plus or minus net interest. The interest accrues in two segments: (1) Interest accrues in favor of the importer on the initial overpayment (\$100) from the date of deposit (January 1) to the date of the refund (May 1); and (2) interest accrues in favor of the Government on the refund overpayment (\$200) from the date of

the refund (May 1) to the date of liquidation (December 1).

(4) If the additional deposit or any portion thereof is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute a payment in excess of the amount initially required to be deposited, the excess deposit shall be treated as a refundable amount on which interest also may be payable (see § 24.36).

(C) If a depository bank notifies Customs by a debit voucher that a Customs account is being debited due to a dishonored check or dishonored Automated Clearinghouse (ACH) transaction, interest shall accrue on the debited amount from the date of the debit voucher to either the date of payment of the debt represented by the debit voucher or the date of issuance of a bill for payment, whichever date is earlier.

(ii) *Interest on overdue bills.* If duties, taxes, fees, and interest are not paid in full within the applicable period specified in § 24.3(e), any unpaid balance shall be considered delinquent and shall bear interest until the full balance is paid.

6. Section 24.11 is revised to read as follows:

**§ 24.11 Notice to importer or owner of increased or additional duties, taxes, fees and interest.**

Any increased or additional duties, taxes, fees or interest found due upon liquidation or reliquidation shall be billed to the importer of record, or to the actual owner if the following have been filed with Customs:

(a) A declaration of the actual owner in accordance with section 485(d), Tariff Act of 1930, as amended (19 U.S.C. 1485(d)), and § 141.20 of this chapter; and

(b) A bond on Customs Form 301 in accordance with § 141.20 of this chapter.

**§ 24.25 [Amended]**

7. In § 24.25, the second sentence of paragraph (a) is amended by removing the words "and fees" and adding, in their place, the words ", fees, and interest".

8. In § 24.36:

a. Paragraph (a) is amended by revising the first sentence, adding a new sentence at the end and adding new paragraphs (a)(1) through (a)(3);

b. The first sentence of paragraph (b) is amended by removing the words "duties or taxes" and adding, in their place, the words "duties, taxes, fees or interest"; and

c. Paragraph (c) is amended by removing the words "duties or internal revenue taxes" and adding, in their place, the words "duties, taxes, fees or interest".

The revisions and additions read as follows:

**§ 24.36 Refunds of excessive duties, taxes, etc.**

(a) When it is found upon, or prior to, liquidation or reliquidation of an entry

or reconciliation that a refund of excessive duties, taxes, fees or interest (at the rate determined in accordance with § 24.3a(c)(1)) is due, a refund shall be prepared in the name of the person to whom the refund is due, as determined under paragraphs (b) and (c) of this section. \* \* \* For purposes of this section:

(1) Except as otherwise provided in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the refund shall include interest on the excess moneys deposited with Customs, and such interest shall accrue from the date the duties, taxes, fees or interest were deposited or, in a case in which a proper claim is filed under 19 U.S.C. 1520(d) and subpart D of Part 181 of this chapter, from the date such claim is filed, to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

*Example: Entry liquidates for a refund*



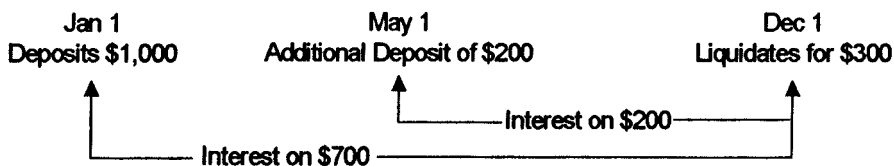
Importer is owed a refund of \$600 plus interest as follows:

The importer makes a \$1,000 initial deposit (January 1) and the entry liquidates for \$400 (December 1). Upon liquidation, the importer will be owed a refund of \$600 plus interest. The interest will accrue from the date of deposit (January 1) to the date of liquidation (December 1).

(i) If an additional deposit of duties, taxes, fees or interest was made prior to liquidation or reliquidation and if any portion of that additional deposit was in excess of the amount required to be deposited, in addition to any other interest accrued under this paragraph (a)(1), the refund also shall include

interest accrued on the excess additional deposit from the date of the additional deposit to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

*Example: Additional deposit made and entry liquidates for a refund*



Importer is owed a refund of \$900 plus interest as follows:

The importer makes a \$1,000 initial deposit (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$300 (December 1). Upon liquidation, the importer will be refunded \$900 plus interest. The interest accrues in two segments: (1) On the additional deposit overpayment (\$200), from the date of the additional deposit (May 1) to the date of liquidation (December 1); and (2) on the initial deposit overpayment (\$700), from the

date of deposit (January 1) to the date of liquidation (December 1).

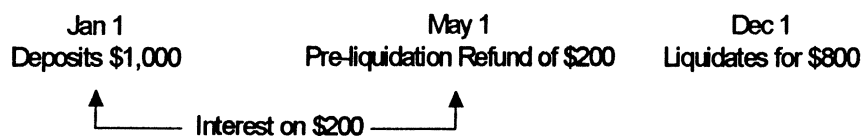
(ii) In the case of a refund of duties, taxes, fees or interest made prior to liquidation, such a refund will include only principal amounts and not any interest thereon. Interest on such principal amounts will be computed at the time of liquidation or reliquidation and shall accrue as follows:

(A) Interest shall only accrue on the amount refunded from the date the

duties, taxes, fees or interest were deposited to the date of the refund if the amount refunded is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute the true excess amount deposited with Customs. An example follows:

*Example: Pre-liquidation refund and entry liquidates for net amount collected*





Importer is owed a refund of interest on \$200 as follows:

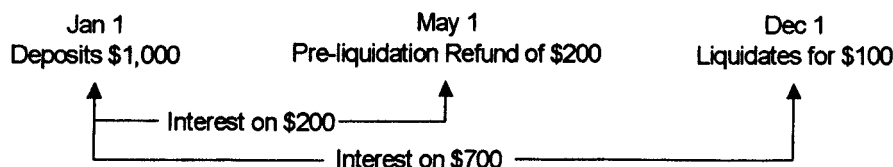
The importer makes a \$1,000 initial deposit (January 1) and receives a pre-liquidation refund of \$200 (May 1) and the entry liquidates for \$800 (December 1). Upon liquidation, the importer will be refunded interest on the \$200 overpayment from the

date of the initial deposit (January 1) to the date of the pre-liquidation refund (May 1).

(B) If the amount refunded is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute less than the true excess amount deposited with Customs, in addition to any other

interest accrued under this paragraph (a)(1), interest also shall accrue on the remaining excess deposit from the date the duties, taxes, fees or interest were deposited to the date of liquidation or reliquidation. An example follows:

Example: Pre-liquidation refund and entry liquidates for an additional refund



Importer is owed a refund of \$700 plus interest as follows:

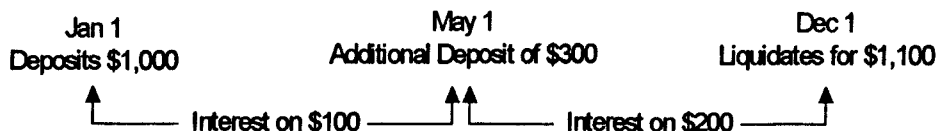
The importer makes a \$1,000 initial deposit (January 1) and receives a pre-liquidation refund of \$200 (May 1) and the entry liquidates for \$100 (December 1). Upon liquidation, the importer will be refunded \$700 plus interest. The interest accrues in two segments: (1) On the pre-liquidation refund (\$200), from the date of deposit

(January 1) to the date of the pre-liquidation refund (May 1); and (2) on the remaining overpayment (\$700), from the date of deposit (January 1) to the date of liquidation (December 1).

(C) If an entry or reconciliation is determined upon liquidation or reliquidation to involve both an initial underpayment and an additional excess

deposit, interest in each case shall be computed separately and the resulting amounts shall be netted for purposes of determining the final amount of interest to be reflected in the refund. An example follows:

Example: Additional deposit made and entry liquidates for a refund



Importer is owed a refund of \$200 plus or minus net interest as follows:

The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$300 (May 1) and the entry liquidates for \$1,100 (December 1). Upon liquidation, the importer will be refunded \$200 plus or minus net interest. The interest accrues in two segments: (1) Interest accrues in favor of the Government on the initial underpayment (\$100) from the date deposit was required (January 1) to the date of the additional deposit (May 1); and (2) interest accrues in favor of the importer on the overpayment (\$200) from the date of the additional deposit (May 1) to the date of liquidation (December 1).

(D) If the amount refunded or any portion thereof exceeds the amount properly refundable as determined upon liquidation or reliquidation of the applicable entry or reliquidation, the excess amount refunded shall be treated as an underpayment of duties, taxes, fees or interest on which interest shall accrue as provided in § 24.3a.

(2) A refund determined to be due upon liquidation or reliquidation, including a refund consisting only of interest that has accrued in accordance with paragraph (a)(1)(ii) of this section, shall be paid within 30 days of the date of liquidation or reliquidation of the applicable entry or reconciliation.

(3) If a refund, including any interest thereon, is not paid in full within the applicable 30-day period specified in paragraph (a)(2) of this section, the refund shall be considered delinquent thereafter and interest shall accrue on the unpaid balance by 30-day periods until the full balance is paid. However, no interest will accrue during the 30-day period in which the refund is paid.

\* \* \* \* \*

## PART 159—LIQUIDATION OF DUTIES

1. The authority citation for Part 159 is revised to read as follows:

**Authority:** 19 U.S.C. 66, 1500, 1504, 1624. Subpart C also issued under 31 U.S.C. 5151.

Sections 159.4, 159.5, and 159.21 also issued under 19 U.S.C. 1315;

Section 159.6 also issued under 19 U.S.C. 1321, 1505;

Section 159.7 also issued under 19 U.S.C. 1557;

Section 159.22 also issued under 19 U.S.C. 1507;

Section 159.44 also issued under 15 U.S.C. 73, 74;

Section 159.46 also issued under 19 U.S.C. 1304;

Section 159.55 also issued under 19 U.S.C. 1558;

Section 159.57 also issued under 19 U.S.C. 1516;

**§§ 159.4, 159.6, 159.7, 159.21, 159.22, 159.44, 159.46, 159.55, 159.57 [Amended]**

2. The parenthetical authority citations at the end of §§ 159.4, 159.5, 159.6, 159.7, 159.21, 159.22, 159.44, 159.46, 159.55, and 159.57 are removed.

3. In § 159.6:  
a. The first sentence of paragraph (a) is amended by removing the words “and taxes” the first time they appear and

adding, in their place, the words "taxes, and interest";

b. The introductory text of paragraph (b) is amended by removing the words "and taxes" wherever they appear and adding, in their place, the words "taxes, and interest";

c. Paragraph (c) is amended by removing the words "and taxes assessed in the liquidation" and adding, in their place, the words "taxes, and interest assessed in the liquidation" and by removing the words "and taxes assessed in the reliquidation" and adding, in their place, the words "taxes, and interest assessed in the reliquidation"; and

d. In paragraph (d), the paragraph heading and the paragraph text are amended by adding "and interest" after "taxes".

## PART 174—PROTESTS

1. The authority citation for Part 174 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1514, 1515, 1624.

### § 174.11 [Amended]

2. In § 174.11, paragraph (c) is amended by adding "including the accrual of interest," after "character".

### § 174.12 [Amended]

3. In § 174.12, paragraph (a)(2) is amended by adding "or receiving a refund of," after "paying".

Approved: July 28, 1999.

**Raymond W. Kelly,**  
*Commissioner of Customs.*

**Dennis M. O'Connell,**  
*Acting Deputy Assistant Secretary of the Treasury.*

[FR Doc. 99-26882 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 3, 5, 10, 20, 50, 56, 58, 207, 310, 312, 316, 600, 601, 607, 610, 640, and 660

[Docket No. 98N-0144]

RIN 0910-AB29

### Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations to eliminate references to establishment licenses and product licenses for all products regulated under the Public Health Service Act (the PHS Act). In lieu of filing an establishment license application (ELA) and product license application (PLA) in order to market a biological product in interstate commerce, a manufacturer will file a single biologics license application (BLA) with the agency. Upon approval of the BLA, a manufacturer will receive a biologics license to market the product in interstate commerce. This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiatives and is intended to reduce unnecessary burdens for industry without diminishing public health protection. This action implements certain sections of the FDA Modernization Act of 1997 (FDAMA).

**DATES:** *Effective date:* The regulation is effective December 20, 1999.

*Compliance Date:* Submit all applications with the Form FDA 356h by December 20, 1999, and submit any application for licensure as a BLA by October 20, 2000.

**FOR FURTHER INFORMATION CONTACT:** Robert A. Yetter, Center for Biologics Evaluation and Research (CBER) (HFM-10), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

### SUPPLEMENTARY INFORMATION:

#### I. Background

In the **Federal Register** of July 31, 1998 (63 FR 40858), FDA proposed to amend the biologics and other drug regulations to eliminate references to the PLA and ELA and to replace such references with the BLA. FDA provided 75 days for comments on the proposed rule. FDA held a public meeting, announced in the **Federal Register** of August 11, 1998 (63 FR 42773), on September 2, 1998, to discuss the BLA/biologics license scheme. FDA also invited the submission of written comments to the docket at the public meeting. The transcript of the public meeting and written comments to the proposed rule are on file in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Prior to the issuance of the proposed rule, FDA had already reviewed its process of licensing biological products and had taken a number of actions to reduce the regulatory burdens imposed

by the licensing process and to make the licensing process more consistent with the process for the approval of new drugs. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA issued a final rule to amend the biologics regulations by eliminating the ELA requirement for the following specified biotechnology and synthetic biological products licensed under section 351 of the PHS Act (42 U.S.C. 262 *et seq.*): (1) Therapeutic deoxyribonucleic acid (DNA) plasmid products; (2) therapeutic synthetic peptide products of 40 or fewer amino acids; (3) monoclonal antibody products for *in vivo* use; and (4) therapeutic recombinant DNA-derived products. That provision applied only to those products that FDA determined under principles articulated in the "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research" (effective on October 31, 1991) to be subject to licensure under section 351 of the PHS Act. Thus, upon approval, manufacturers of the specified biotechnology and synthetic biological products received a single biologics license instead of a product license and an establishment license (see § 601.2(c) (21 CFR 601.2(c))).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised Form FDA 356h entitled "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use." Form FDA 356h was revised as a "Reinventing Government" initiative to harmonize application procedures between CBER and the Center for Drug Evaluation and Research (CDER) as outlined in the President's November 1995 National Performance Review Report entitled "Reinventing the Regulation of Drugs Made From Biotechnology." In the notice, FDA advised that applicants for biologics licenses for products specified in § 601.2(c) as well as autologous somatic cell therapy products could begin to use Form FDA 356h immediately and were required to do so beginning January 8, 1998. FDA advised applicants for licenses for other biological products that the agency would announce in the future when they can voluntarily begin to use and will be required to use Form FDA 356h. Upon approval of a BLA submitted on Form FDA 356h, FDA will issue a single biologics license. FDA believes that this licensing procedure will greatly simplify the application process, harmonize application procedures with those of CDER, and reduce industry and agency paperwork burdens. As a consequence of this final

rule, all manufacturers requesting approval to introduce, or deliver for introduction, a biological product into interstate commerce must use Form FDA 356h to submit a BLA in lieu of separate establishment and product applications.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 123 of FDAMA, in pertinent part, amended section 351 of the PHS Act to specify that a biologics license shall be in effect for a biological product prior to such product's introduction into interstate commerce. FDAMA thereby statutorily codified FDA's administrative BLA/biologics license "Reinventing Government" initiative. Section 123(a)(1) of FDAMA further states that the Secretary of Health and Human Services (the Secretary) (delegated to the Commissioner of Food and Drugs at 21 CFR 5.10(a)(5)) shall approve a "biologics license application" on the basis of a demonstration that the biological product that is the subject of the application is safe, pure, and potent; and the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to ensure that the biological product continues to be safe, pure, and potent.

With the consolidation of the ELA's and PLA's into a single BLA, the amount of information formerly included in the ELA will be reduced, but not eliminated. Much of the information previously reviewed in an ELA at FDA will be reviewed by FDA investigators at the manufacturing site during a preapproval inspection. Some information formerly included in the ELA will now be submitted as "chemistry, manufacturing, and controls" (CMC) information or under the "establishment description" section of Form FDA 356h. The type and amount of information related to the establishment will vary according to the specific biological product for which licensure is being requested. To describe what information should be included for each type of biological product, CBER has prepared a series of guidance documents. The following guidance documents are available: (1) "Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use" (61 FR 56243, October 31, 1996); (2) "Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products" (62 FR 1460, January

10, 1997); (3) "Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances" (issued on the internet, November 1994); (4) "Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls and Establishment Description Information for a Vaccine or Related Product" (64 FR 518, January 5, 1999); (5) "Guidance for Industry for the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma, or Serum-Derived Products" (64 FR 7896, February 17, 1999); (6) "Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls, and Establishment Description Information for a Biological In Vitro Diagnostic Product" (64 FR 11023, March 8, 1999); (7) "Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls, and Establishment Description Information for an Allergenic Extract or Allergen Patch Test" (64 FR 20006, April 23, 1999); and (8) "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls, and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use" (64 FR 25049, May 10, 1999). All of these guidance documents can be downloaded from the CBER Guidelines/Guidance document World Wide Web page at "<http://www.fda.gov/cber/guidelines.htm>". These guidance documents can also be obtained by written request to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. These documents may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

## **II. Highlights of Proposed Rule**

### **A. Introduction**

FDA licenses biological products under the authority of section 351(a) of the PHS Act. The PHS Act requires that biological products be licensed and be

safe, pure, potent, and manufactured in facilities designed to ensure that the product continues to be safe, pure, and potent. The PHS Act does not specify the license application forms that manufacturers must submit to FDA. Except for the biological products listed under § 601.2(c), FDA, in the past, has required manufacturers to submit a PLA and an ELA (or a PLA and a supplement to an existing ELA) for each biological product. Accordingly, upon approval, FDA issued two licenses for each product.

In the proposed rule of July 31, 1998, FDA proposed changes to the regulations intended to implement use of the BLA and to implement FDAMA. The proposed rule would also change certain definitions to be more consistent with FDAMA and eliminate references to the PLA and ELA. In the following sections of this document, FDA outlines in greater detail the provisions of the proposed rule.

### **B. Definitions and Deletion of Terms**

In order to reduce any confusion that may result from use of the term "facility" in section 351 of the PHS Act as amended by FDAMA, FDA proposed to amend the definition of "establishment" in § 600.3(w) (21 CFR 600.3(w)) to clarify that the term has the same meaning as "facility" in section 351 of the PHS Act. FDA also proposed to amend the definition of "standards" in § 600.3(n) to indicate that the term refers to specifications and procedures established in BLA's designed to ensure the continued safety, purity, and potency of biological products as well as adherence to specifications and procedures in applicable regulations. Establishing standards in the BLA is consistent with FDA's previous effort to streamline the license review process by deleting certain additional standards in the biologics regulations (see 61 FR 40153, August 1, 1996). This proposed change to § 600.3(n) also would reduce confusion in the biologics regulations by establishing consistency with FDA's current regulation at 21 CFR 601.5(b)(4) regarding the revocation of licenses. FDA proposed to delete the term "licensee" as used in the biologics regulations in order to reduce confusion and to make clear that it is the licensed manufacturer who is responsible for compliance with product and establishment requirements. The term "licensed manufacturer" would be inserted in all instances that currently read "licensee."

### *C. Elimination of PLA/ELA and Implementation of BLA*

FDA proposed that the terms "biologics license" or "biologics license application" be substituted in lieu of references to PLA's and ELA's and product and establishment licenses in all regulations in 21 CFR chapter I. In a few instances, references to product and establishment licenses would be retained for historical accuracy, e.g., § 601.25 (21 CFR 601.25) and 21 CFR 601.26.

Under the proposed rule, a manufacturer applying for approval to market a biological product under section 351 of the PHS Act would submit to FDA the appropriate establishment and product information on the recently approved Form FDA 356h. Manufacturers would no longer be required to submit product or establishment information on one of the many different PLA and ELA forms formerly in use. Upon approval of the BLA, FDA would issue an approval letter that in general terms states that FDA grants the licensed manufacturer a biologics license to manufacture the particular biological product. FDA would not issue license certificates separate from the approval letter as is current agency practice. The approval letter would serve as the functional equivalent of a biologics license within the meaning of section 351 of the PHS Act.

Under proposed § 601.2(a), manufacturers would list in the BLA the addresses of all locations of manufacture of a biological product. FDA believes this will simplify and clarify the licensing processes by having necessary establishment information in the BLA and also by allowing FDA to approve all locations involved in the manufacture of the product without having to issue an establishment license for each location.

Under proposed § 601.9(c), for manufacturers of some biological products that would be able to list multiple products in a single BLA, (such as blood and blood components and nonstandardized allergenic products) and for which FDA will issue a single biologics license to the manufacturer for more than one product, FDA would be able to license compliant locations and products and exclude noncompliant locations.

### *D. Radioactive Biological Products*

FDA proposed to amend § 601.2(b) to clarify procedures for submitting an application for marketing approval for a radioactive biological product in order to help ensure consistency with current

CBER and CDER policies and procedures. The regulation would clarify when a manufacturer of a radioactive biological product should submit a new drug application (NDA) to CDER or a BLA to CBER. The regulation provides that when the biological component of a radioactive coupled antibody determines the site of action, normally a BLA would be submitted. The regulation will provide sufficient flexibility to take into account situations that may arise in the future where the scientific issues associated with a radionuclide or other chemically synthesized component are more significant than the scientific issues associated with the biological component. In such cases, jurisdiction will be determined in accordance with principles articulated in the "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research" of October 31, 1991. The proposed changes should not be construed as an attempt to address or implement the requirements of section 122 of FDAMA, "Requirements for Radiopharmaceuticals."

FDA is also amending § 310.4 (21 CFR 310.4) to make it consistent with § 601.2(b). Revisions to the proposed changes to § 310.4 have been made for clarity. Certain changes to both § 310.4(a) and (b) are necessary in order to make congruous the regulations that describe whether CBER or CDER will have primary jurisdiction over a radioactive biological product. The amendment to § 310.4(b) is prospective and does not alter the approval mechanism of any currently approved radioactive biological products that have approved NDA's or approved establishment and product licenses. Section 310.4(a) is amended to make it consistent with § 601.2(b) and to clarify that if any biological product has an approved license under section 351 of the PHS Act, it is not required to have an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355).

### *E. Current Good Manufacturing Practice Requirements*

FDA discussed in the preamble to the proposed rule the applicability of current good manufacturing practices (CGMP) requirements for biological products. For clarity FDA proposed in § 601.2(d) that the CGMP requirements in parts 210, 211, 600, 606, and 820 (21 CFR parts 210, 211, 600, 606, and 820) are included, as applicable, as part of the establishment requirements for the production of a biological product.

### **III. Comments on the Proposed Rule and FDA Responses**

FDA received two letters of comment in response to the proposed rule; one letter from an organization representing the blood and blood component industry and another from a manufacturer of biological products. Comments received and FDA's responses to the comments are discussed below. There were also a few technical changes, to be consistent with other changes in this rulemaking or to be consistent with statutory language in FDAMA, made to the following regulations: 21 CFR 50.3(b)(12), 56.102(b)(11), 58.3(e)(13); §§ 600.81, 601.2, and 601.21 (21 CFR 601.21). FDA is also revising 21 CFR 601.22 to remove wording that was inadvertently added to the regulation in the proposed rule that implied that either of two requirements must be met. The change eliminates this ambiguity and reinstates the original intent that both requirements must be met.

1. A comment was supportive of the concept of a BLA and use of the Form FDA 356h but strongly urged FDA to ensure that the intended paperwork reduction and efficiency goals are achieved. The comment stated that the simplification of the BLA will be affected by how supplemental applications are handled and expressed concern that this be adequately addressed. The comment specifically requested that in implementing the BLA for blood and blood components that one supplement to the BLA be acceptable to report a change in the manufacturing of Platelets, Pheresis for all manufacturing locations.

FDA agrees that it is important to implement the rule in a manner that will reduce unnecessary burdens; accordingly the agency is implementing several mechanisms for ensuring that this is the case. Manufacturers of some biological products will be able to list multiple products in a BLA and FDA will issue a single biologics license to the manufacturer for more than one product. FDA intends to use this approach generally with products that both have been on the market for a long period of time and that FDA has considerable knowledge and expertise regulating. Currently, only products such as blood and blood components and nonstandardized allergenic products will be handled in a single BLA. Therefore, a manufacturer of blood and blood components will only need to submit one BLA to request approval to market one or more blood or blood components, (e.g., Whole Blood, Platelets, Plasma, Red Blood Cells, and

Cryoprecipitated AHF). FDA believes this consolidation of forms and submissions will result in a reduced regulatory burden for the blood industry because information previously duplicated in the many blood and blood component product and establishment applications would be submitted only once in the BLA.

With regard to manufacturing changes, the BLA system will simplify submission of supplements to blood and blood component applications.

Currently, manufacturers desiring to make a single manufacturing change that would affect multiple products are required to submit a supplement to each individual product and establishment application. Under the final rule, a manufacturer would only need to submit one supplement to the BLA. For example, under the current PLA/ELA system if a manufacturer desired to make a single change to the irradiation procedure for its Whole Blood, Red Blood Cells, Platelets, and Plasma products manufactured at 3 locations, the manufacturer would be required to submit 12 supplements to 4 PLA's, i.e., a separate supplement for each blood component manufactured at each location. Under the final rule, the manufacturer would only be required to submit one supplement to the BLA describing the change for all of the products and locations involved. Of course, all data (including applicable validation and quality control testing) and information related to all the affected products and locations would be expected to be present in the supplement. Section 123 of FDAMA states, in part, that the Secretary shall approve a BLA on the basis of a demonstration that the biological product that is the subject of the application is safe, pure, and potent; and the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to ensure that the biological product continues to be safe, pure, and potent. FDA intends to ensure that the final rule will be properly implemented and is providing adequate training and management oversight to ensure that this happens.

2. One comment requested the elimination of the use of the Form FDA 2567, Transmittal of Labels and Circulars, as being duplicative of Form FDA 356h.

FDA disagrees that the form is duplicative. FDA Form 2567 is used for any submission of labeling, including promotional labeling. This form (OMB Control No. 0910-0039) contains information that is not requested in the Form FDA 356h, which is necessary for

the adequate tracking of labeling submissions to FDA. It provides specific identification of the labeling changes, including revision number and the type of labeling and provides a check list for the type of changes that have been made to the labeling. The form provides a clear, simple method for transmitting comments on the labeling to and from the manufacturers allowing for quick return of comments and easy identification of sequential revisions.

3. One comment stated that the "Draft Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use'" (63 FR 37401, July 10, 1998) requires, for the first time, submission of information regarding certain manufacturing standard operating procedures (SOP's), contracts, organizational characteristics, organization diagrams, physical plant, major equipment, and quality assurance.

FDA disagrees in part with this comment. Guidance documents do not set forth requirements; they provide the agency's current thinking on a topic and are nonbinding. A review of SOP's, physical plant information, and information on contracts have always been part of an assessment of a product's safety, purity, and potency. FDA has the authority to require sponsors to submit such information in license applications under section 351 of the PHS Act and 21 CFR part 601. In the more recent past, FDA has found that inadequate organizational/managerial oversight and quality assurance problems at firms have resulted in firms being out of compliance with the regulations applicable to blood and blood components and have been the cause of problems leading to significant enforcement action by the agency. FDA believes it is important to review information related to the managerial/organizational oversight and quality assurance in order to ensure that a firm can manufacture products that meet the applicable regulatory and statutory requirements. Therefore, FDA will review such information as part of the BLA. FDA believes that the burden associated with the submission of such information will be minimal. Describing organizational aspects can be done through the use of organizational charts, and under CGMP regulations, quality assurance is already a requirement. The

submission of descriptions of such organizations should require minimal time for gathering and preparing the information. In addition, since other information previously reviewed as part of the PLA and ELA will not be required to be included in a BLA, FDA estimates that the net effect is no increase in burden or a slightly lower burden. For example, information that will no longer be submitted in a BLA but should, as appropriate, be available for an establishment inspection includes, but is not limited, to such information as: (1) Floor plans of facilities, auxiliary facilities and self-contained mobile units to show locations of major equipment, hand washing facilities and restrooms; (2) Heating, ventilation, and air conditioning information; (3) curriculum vitae for physicians, physician substitutes, authorized officials and their alternates, and managers; (4) "statement of understanding" from physicians and authorized officials; (5) proof of state licensure of physicians; (6) physician substitute certification of training and cardiopulmonary resuscitation; (7) supervisor qualifications and number of people supervised in the areas of donor suitability, blood collection, laboratory processing, and testing; (8) description of any other uses for the area where blood collection or processing occurs; (9) description of provisions for housekeeping, pest control, and lighting; (10) description of records maintenance method, including when they are made, how long they are stored, and how they are maintained to permit effective recall; and (11) copy of the certificate of incorporation. FDA is currently reviewing comments on the draft CMC guidance and will consider the comments in any revision made to the "Draft Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.'"

4. One comment supported the proposed revision to § 601.21 but recommended that the regulation reference the appropriate section of the act applicable to investigational device exemptions.

FDA agrees with the comment and is amending § 601.21 in the final rule to reference section 520(g) of the act (21 U.S.C. 360j(g)) that provides for exemption of devices for investigational use.

FDA has considered all comments received in response to the proposed rule and has determined that the proposed rule should be issued as a final rule. Accordingly, FDA is issuing as a final rule changes to the biologics regulations that provide for the use of a "biologics license application" and "biologics license" for the licensure of all products under section 351 of the PHS Act.

#### IV. Effective Dates and Other Implementation Issues

FDA is providing a 10-month transition period for implementation of the BLA. FDA recognizes that it may take applicants time to switch format from PLA's and ELA's to BLA's. Any PLA and ELA for a biological product pending on the effective date of these regulations will be reviewed as submitted. Notwithstanding the new regulations, new submissions by the manufacturer will not be necessary for these products. FDA will continue to accept PLA's and ELA's in lieu of a BLA until October 20, 2000, of this final rule. However, all applications submitted to the agency after the effective date of the final rule will be required to include all information indicated in Form FDA 356h in order for the application to be considered as complete. PLA's and ELA's received after the effective date of the final rule will be administratively handled by FDA as a BLA. If the PLA and ELA are sufficient for licensure, FDA will issue a biologics license. Any manufacturer planning to file a PLA and an ELA during the 10-month time period after the effective date of these regulations should contact FDA for further guidance.

Under new § 601.2(e), a manufacturer already holding an approved ELA and PLA for a biological product will not be required to file supplements to comply with the amended regulations. The approved PLA together with portions of the approved ELA relevant to the new requirements for the BLA, will be deemed to constitute a BLA under section 351 of the PHS Act.

#### V. Analysis of Impacts

##### A. Reduction in Burden

The use of the harmonized Form FDA 356h for all biological products and drugs regulated by CBER and CDER will reduce burden on industry by enabling manufacturers to submit applications for biological products and drugs in a consistent format.

Manufacturers intending to introduce biological products into interstate commerce will no longer have to prepare a PLA and an ELA to submit to

the agency for approval. The amount of information that manufacturers will need to provide in a BLA will be less than that previously required in a PLA and ELA. These changes will enable manufacturers to devote fewer resources to submitting documentation to the agency. Much of the information previously reviewed in an ELA at FDA will be reviewed by FDA investigators at the manufacturing site during a preapproval inspection. According to many biological product manufacturers, preparation, submission, and approval of a separate PLA and ELA for each biological product added substantially to the cost of licensing the product.

The inclusion of reference to parts 210, 211, 600, 606, and 820 in the final rule as establishment requirements only serve to clarify existing requirements and will not impose any additional burden on industry. Biological products regulated under section 351 of the PHS Act, are already subject to the CGMP's in parts 600, 606 and, as applicable, parts 210 and 211, or 820.

##### B. Review Under Executive Order 12866 and the Regulatory Flexibility Act

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impact; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. In addition, the rule is a significant regulatory action as defined in Executive Order 12866 and is subject to review because it deals with a novel policy issue.

In accordance with the principles of Executive Order 12866, the overall result of the rule will be a substantial reduction in burdens on a manufacturer filing an application to market a biological product. In addition, FDA anticipates that the rule will facilitate a manufacturer's ability to improve its licensed products and methods of manufacture by decreasing the burden and cost associated with filing applications and supplements.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because, as stated previously, the overall result of the rule will be a

substantial reduction in reporting burdens, the agency certifies that the rule would not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

##### C. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and the respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

**Title:** Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License.

**Description:** This final rule revises the regulations regarding the procedures for application for approval to market a biological product regulated under section 351 of the PHS Act. Under the regulations, a manufacturer will submit to FDA the appropriate establishment and product information in a single BLA in lieu of filing a separate ELA and PLA. Upon approval of the BLA, a manufacturer would receive a single biologics license to market the product in interstate commerce.

**Description of Respondents:** Manufacturers of biological products.

The final rule amends the regulations for filing an application to market a biological product under § 601.2 to eliminate references to establishment licenses and product licenses for all products regulated under the PHS Act. The final rule will require biologics manufacturers to file a single BLA, rather than either an ELA or PLA, to market a biological product. The agency estimates that the total average paperwork burden for manufacturers filing one application that consolidates the information currently required under both the PLA and ELA will decrease approximately 10 percent. The estimate reduces the number of annual responses from a combined PLA/BLA/ELA total of 76 to a BLA total of 60. This estimate is derived from the total number of license applications received

by FDA in fiscal year (FY) 1997 (76) minus the total number of ELA's filed in the same period (17). Based on information provided by industry, the time estimated to prepare an application for FDA approval to market a product is approximately 1,600 hours. In addition to § 601.2, there are other regulations in the final rule that relate to certain information to be included in a license application including § 640.21(c) (21 CFR 640.21(c)), § 640.22(c) (21 CFR 640.22(c)), 21 CFR 640.65(a), and 660.21(a)(3) and (d). The burden associated with the information collection requirements in these regulations is included in the following reporting burden estimate for § 601.2.

The regulation also makes several technical amendments to conform the language throughout the biological product regulations to the changes made final here for § 601.2. Specifically, the final rule makes the following technical term changes: References to product and establishment license, and product and establishment applications are replaced with "biologics license" or "biologics license application;" and "licensee" is replaced with "licensed manufacturer." These technical changes do not have an impact on either the substantive requirements or the paperwork burden of these requirements, each of which carry OMB clearance numbers as follows: 21 CFR 207.20(c) and 207.21(a) (0910-0045); §§ 600.80(c)(2) and 600.81 (0910-0308); § 601.25(b)(3) (0910-0039); 21 CFR 607.20(b) and 607.21 (0910-0052); and 21 CFR 610.63 and 640.71(b)(1) (0910-0116).

The following regulations relate to the submission of additional information in certain supplements to a BLA. Regulations in 21 CFR 600.15(b) and 610.53(d) require submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. The preparation of an exemption request is estimated to be 8 hours; however, no requests were received by the agency under either regulation in FY 1997. To account for the rare instance in which a request for an exemption may be made, the agency has estimated one respondent per year in Table 1 of this document. Section 640.6 (21 CFR 640.6) requires that an applicant submit a request to make a certain modification of Whole Blood. The number of supplements relating to Whole Blood filed by an applicant in FY 1997 totaled 74. Because the agency could not easily determine the number of supplements filed specific to § 640.6, the estimate below is based on last year's total number of supplements

related to Whole Blood, regardless of whether the supplement was filed specific to § 640.6.

The remaining regulations, §§ 640.21(c), 640.22(c), 21 CFR 640.64(c), and 640.74(a) and (b)(2), refer to information that is collected under § 601.12, (OMB Control No. 0910-0315) under which the collection of information burden is calculated. Moreover, the final rule makes only technical changes to these regulations. For example, the term "product license" is changed to "biologics license," and the term "product licensee" is changed to "licensed manufacturer."

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection provisions of the proposed rule (63 FR 40858). One letter of comment on the information collection provisions was submitted to OMB. Most of the comments submitted to OMB were the same as those submitted directly to FDA in response to the proposed rule. FDA's responses to these comments are found above in section III of this document. Responses to additional comments in the letter received by OMB that were not addressed previously are addressed in the following paragraphs.

1. A comment pointed out that few new BLA's for blood and blood components will be submitted to the agency. More frequently changes to already approved applications are submitted as supplements. These supplements will now use Form FDA 356h for submission to the agency. The comment stated if Form FDA 356h is merely substituted for the current forms and manufacturers must continue to file a supplement for each product at each location, the paperwork will actually increase because of the increased CMC and establishment requirements.

FDA agrees that few new BLA's for blood and blood components are submitted to the agency. However, FDA disagrees that the burden will increase. Previously, manufacturers desiring to make a single manufacturing change that would affect multiple products were required to submit a supplement to each individual product and establishment application. Under this final rule a manufacturer would only need to submit one supplement to the BLA. For example, under the current PLA/ELA system, if a manufacturer desired to make a single change to the irradiation procedure for its Whole Blood, Red Blood Cells, Platelets, and Plasma products manufactured at 3 locations, the manufacturer would be required to submit 12 supplements to 4 PLA's. Under the proposed BLA system,

the manufacturer would only be required to submit one supplement to the BLA describing the change for all of the products and locations involved. Therefore, fewer supplements should be submitted by applicants. The size of the decrease in supplements will depend on how the applicant bundles the submissions. At the time of submission of a supplement, FDA expects that all data and information pertinent to the supplement be present or the FDA may refuse to file the application (see the guidance entitled "Center for Biologics Evaluation and Research (CBER): Refusal to File (RTF) Guidance for Product License Applications (PLA's) and Establishment License Applications (ELA's)" (58 FR 38770, July 20, 1993)). Therefore, if an applicant wishes to submit a change affecting multiple locations in one supplement, and all data and information supporting the change at those locations are present in the supplement, FDA will accept such a submission. FDA, therefore, estimates that there will be an overall reduction in burden associated with this final rule.

2. Another comment stated that the number of respondents and supplement submissions, and the hours per submission were severely underestimated by FDA. The comment expressed concern that FDA was unable to specifically enumerate the number of submissions made under § 640.6 and suggested that this was "indicative of a larger problem." The comment described FDA's approach to burden estimates as disturbing for other reasons such as not addressing supplements for products other than Whole Blood, and because the agency's internal tracking, accounting, and documentation systems may be inadequate. The comment stated that FDA had trouble distinguishing between supplemental license applications submitted under §§ 640.6 and 601.12. For the purposes of burden hour development, the distinction between supplements submitted under § 640.6 and those under § 601.12 is somewhat artificial because the burden for the regulated community to prepare the supplement is identical regardless of the section under which such information is submitted.

The comment has misinterpreted the estimate. In preparing this burden estimate, FDA estimated the burden for those sections of the regulations being amended, including § 640.6. No changes in § 601.12 were included in this rulemaking, therefore FDA has not estimated the burden of this section which already has an approved OMB control number (0910-0315). The burden associated with the preparation of supplemental applications is also



included in the estimate for § 601.12 and is outside the scope of this rule. Since § 640.6 applies specifically to Whole Blood, an estimate as seen in Table 1 of this document is limited to only Whole Blood submissions and the associated reporting burden hours. The number of respondents reflects the number of FY 1997 supplements submitted specifically for Whole Blood, and the 8 hours is an accurate estimate for this type of submission. For

purposes of carrying out its obligations for the review of applications, FDA continues to believe that it is unnecessary to keep separate track of those applications submitted under § 640.6, because review of these supplemental applications is not different from other supplemental applications submitted under § 601.12. Because FDA's current tracking system does not allow a search of the data base that would identify accurately the

number of Whole Blood supplements submitted under § 640.6, FDA looked at the number of all supplements related only to Whole Blood, which is the scope of this regulation, and conservatively estimated the burden to account for more rather than fewer burden hours. Therefore, the estimated burden hours are likely to be higher than those that may actually occur.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2	60	1	60	1,600	96,000
600.15(b)	1	1	1	8	8
610.53(d)	1	1	1	8	8
640.6	74	1	74	8	592

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of the final rule have been submitted to OMB for review. Prior to the effective date of the final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### D. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects

##### 21 CFR Part 3

Administrative practice and procedure, Biologics, Drugs, Medical devices.

##### 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

##### 21 CFR Part 10

Administrative practice and procedure, News media.

##### 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

##### 21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

##### 21 CFR Part 56

Human research subjects, Reporting and recordkeeping requirements, Safety.

##### 21 CFR Part 58

Laboratories, Reporting and recordkeeping requirements.

##### 21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

##### 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

##### 21 CFR Part 316

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

##### 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

##### 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

##### 21 CFR Part 607

Blood.

##### 21 CFR Parts 610 and 660

Biologics, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 3, 5, 10, 20, 50, 56, 58, 207, 310, 312, 316, 600, 601, 607, 610, 640, and 660 are amended as follows:

#### PART 3—PRODUCT JURISDICTION

1. The authority citation for 21 CFR part 3 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262.

2. Section 3.2 is amended by revising paragraph (k) to read as follows:

##### § 3.2 Definitions.

\* \* \* \* \*

(k) *Premarket review* includes the examination of data and information in an application for premarket review described in sections 505, 510(k), 513(f), 515, or 520(g) or 520(l) of the act or section 351 of the Public Health Service Act of data and information contained in any investigational new drug (IND) application, investigational device exemption (IDE), new drug application (NDA), biologics license application, device premarket notification, device reclassification petition, and premarket approval application (PMA).

\* \* \* \* \*



**PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

3. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

4. Section 5.58 is amended by revising paragraph (a)(3) to read as follows:

**§ 5.58 Orphan products.**

(a) \* \* \*

(3) Applications for biologics licenses for biological products; or

\* \* \* \* \*

5. Section 5.67 is amended by revising paragraphs (a), (b), and (c) to read as follows:

**§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.**

\* \* \* \* \*

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

\* \* \* \* \*

**PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES**

6. The authority citation for 21 CFR part 10 continues to read as follows:

**Authority:** 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

7. Section 10.50 is amended by revising paragraph (c)(19) to read as follows:

**§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.**

\* \* \* \* \*

(c) \* \* \*

(19) Section 351(a) of the Public Health Service Act on a biologics license for a biological product.

\* \* \* \* \*

**PART 20—PUBLIC INFORMATION**

8. The authority citation for 21 CFR part 20 continues to read as follows:

**Authority:** 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

9. Section 20.100 is amended by revising paragraph (c)(24) to read as follows:

**§ 20.100 Applicability; cross-reference to other regulations.**

\* \* \* \* \*

(c) \* \* \*

(24) Applications for biologics licenses for biological products, in § 601.51 of this chapter.

\* \* \* \* \*

**PART 50—PROTECTION OF HUMAN SUBJECTS**

10. The authority citation for 21 CFR part 50 continues to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e; 42 U.S.C. 216, 241, 262, 263b–263n.

11. Section 50.3 is amended by revising paragraph (b)(12) to read as follows:

**§ 50.3 Definitions.**

\* \* \* \* \*

(b) \* \* \*

(12) An application for a biologics license, described in part 601 of this chapter.

\* \* \* \* \*

**PART 56—INSTITUTIONAL REVIEW BOARDS**

12. The authority citation for 21 CFR part 56 continues to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

13. Section 56.102 is amended by revising paragraph (b)(11) to read as follows:

**§ 56.102 Definitions.**

\* \* \* \* \*

(b) \* \* \*

(11) An application for a biologics license, described in part 601 of this chapter.

\* \* \* \* \*

**PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES**

14. The authority citation for 21 CFR part 58 continues to read as follows:

**Authority:** 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

15. Section 58.3 is amended by revising paragraph (e)(13) to read as follows:

\* \* \* \* \*

(e) \* \* \*

(13) An application for a biologics license, described in part 601 of this chapter.

\* \* \* \* \*

**PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION**

16. The authority citation for 21 CFR part 207 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 360, 360b, 371, 374; 42 U.S.C. 262.

17. Section 207.20 is amended by revising paragraph (c) to read as follows:

**§ 207.20 Who must register and submit a drug list.**

\* \* \* \* \*

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or operator of an establishment is required to register before the agency approves it: A new drug application, a new animal drug application, a medicated feed application, or a biologics license application.

\* \* \* \* \*

18. Section 207.21 is amended by revising the second sentence of paragraph (a) to read as follows:

**§ 207.21 Times for registration and drug listing.**

(a) \* \* \* If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, new animal drug application, medicated feed application, or a biologics license application. \* \* \*

\* \* \* \* \*

**PART 310—NEW DRUGS**

19. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

20. Section 310.4 is revised to read as follows:

**§ 310.4 Biologics; products subject to license control.**

(a) If a drug has an approved license under section 351 of the Public Health

Service Act (42 U.S.C. 262 *et seq.*) or under the animal virus, serum, and toxin law of March 4, 1913 (21 U.S.C. 151 *et seq.*), it is not required to have an approved application under section 505 of the act.

(b) To obtain marketing approval for radioactive biological products for human use, as defined in § 600.3(ee) of this chapter, manufacturers must comply with the provisions of 601.2(b) of this chapter.

21. Section 310.503 is amended by revising the first sentence of paragraph (b) to read as follows:

**§ 310.503 Requirements regarding certain radioactive drugs.**

(b) It is the opinion of the Nuclear Regulatory Commission, and the Food and Drug Administration that this exemption should not apply for certain specific drugs and that these drugs should be appropriately labeled for uses for which safety and effectiveness can be demonstrated by new drug applications or through licensing under the Public Health Service Act (42 U.S.C. 262 *et seq.*) in the case of biologics. \*

**PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

22. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

23. Section 312.3 is amended in paragraph (b) by revising the definition for *Marketing application* to read as follows:

**§ 312.3 Definitions and interpretations.**

(b) *Marketing application* means an application for a new drug submitted under section 505(b) of the act or a biologics license application for a biological product submitted under the Public Health Service Act.

**PART 316—ORPHAN DRUGS**

24. The authority citation for 21 CFR part 316 continues to read as follows:

**Authority:** 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

25. Section 316.3 is amended by revising paragraph (b)(9) to read as follows:

**§ 316.3 Definitions.**

(b) \*

(9) *Marketing application* means an application for approval of a new drug filed under section 505(b) of the act or an application for a biologics license submitted under section 351 of the Public Health Service Act (42 U.S.C. 262).

**PART 600—BIOLOGICAL PRODUCTS: GENERAL**

26. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

27. Section 600.3 is amended by revising paragraphs (n) and (w) to read as follows:

**§ 600.3 Definitions.**

(n) The word *standards* means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter or established in the biologics license application designed to insure the continued safety, purity, and potency of such products.

(w) *Establishment* has the same meaning as “facility” in section 351 of the Public Health Service Act and includes all locations.

28. Section 600.15 is amended by revising paragraph (b) to read as follows:

**§ 600.15 Temperatures during shipment.**

(b) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, approved by the Director, Center for Biologics Evaluation and Research.

29. Section 600.21 is amended by revising the first sentence to read as follows:

**§ 600.21 Time of inspection.**

The inspection of an establishment for which a biologics license application is pending need not be made until the establishment is in operation and is manufacturing the complete product for which a biologics license is desired.

30. Section 600.80 is amended by revising the first sentence of paragraph (b), the first and second sentences of paragraph (c)(2)(i), and by revising paragraphs (g) and (j) to read as follows:

**§ 600.80 Postmarketing reporting of adverse experiences.**

(b) *Review of adverse experiences.* Any person having a biologics license under § 601.20 of this chapter shall promptly review all adverse experience information pertaining to its product obtained or otherwise received by the licensed manufacturer from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. \*

(c) \*

(2) *Periodic adverse experience reports.* (i) The licensed manufacturer shall report each adverse experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The licensed manufacturer shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of issuance of the biologics license) and each annual report within 60 days of the anniversary date of the issuance of the biologics license. \*

(g) *Multiple reports.* A licensed manufacturer should not include in reports under this section any adverse experience that occurred in clinical trials if they were previously submitted as part of the biologics license application. If a report refers to more than one biological product marketed by a licensed manufacturer, the licensed manufacturer should submit the report to the biologics license application for the product listed first in the report.

(j) *Revocation of biologics license.* If a licensed manufacturer fails to establish and maintain records and make reports required under this section with respect to a licensed biological product, FDA may revoke the biologics license for such a product in accordance with the procedures of 601.5 of this chapter.

31. Section 600.81 is amended by revising the first sentence to read as follows:

**§ 600.81 Distribution reports.**

The licensed manufacturer shall submit information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. \*

**PART 601—LICENSING**

32. The authority citation for 21 CFR part 601 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec.122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

**§ 601.1 [Removed]**

33. Section 601.1 *Two forms of licenses* is removed.

34. Section 601.2 is revised to read as follows:

**§ 601.2 Applications for biologics licenses; procedures for filing.**

(a) *General.* To obtain a biologics license under section 351 of the Public Health Service Act for any biological product, the manufacturer shall submit an application to the Director, Center for Biologics Evaluation and Research, on forms prescribed for such purposes, and shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance; statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter; or was not subject to such requirements in accordance with § 56.104 or § 56.105, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter. A full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product for introduction or delivery for introduction into interstate commerce; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); specimens of the labels, enclosures, and containers, and if applicable, any Medication Guide required under part 208 of this chapter proposed to be used for the product; and the address of each location involved in the manufacture of the biological product shall be listed in the biologics license application. The applicant shall also include a financial certification or disclosure statement(s) or both for clinical investigators as

required by part 54 of this chapter. An application for a biologics license shall not be considered as filed until all pertinent information and data have been received from the manufacturer by the Center for Biologics Evaluation and Research. The applicant shall also include either a claim for categorical exclusion under § 25.30 or § 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section. The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. An application for any of the following specified categories of biological products subject to licensure shall be handled as set forth in paragraph (c) of this section:

(1) Therapeutic DNA plasmid products;

(2) Therapeutic synthetic peptide products of 40 or fewer amino acids;

(3) Monoclonal antibody products for in vivo use; and

(4) Therapeutic recombinant DNA-derived products.

(b) *Radioactive biological products.* To obtain marketing approval for a radioactive biological product, as defined in § 600.3(ee) of this chapter, the manufacturer of such product shall comply with the following:

(1) An applicant for a radioactive coupled antibody, which means a product that consists of an antibody component coupled with a radionuclide component (or an antibody component intended solely to be coupled with a radionuclide) in which both components provide a pharmacological effect but the biological component determines the site of action, shall submit a biologics license application to the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, except if, as determined by FDA, there are significant scientific issues associated with the radionuclide or other chemically synthesized component, in which case a new drug application shall be submitted to the Center for Drug Evaluation and Research, Food and Drug Administration;

(2) An applicant for a radioactive biological product other than as described in paragraph (b)(1) of this section, shall submit a new drug application to the Center for Drug Evaluation and Research, Food and Drug Administration.

(c)(1) To obtain marketing approval for a biological product subject to licensure which is a therapeutic DNA

plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product, an applicant shall submit a biologics license application in accordance with paragraph (a) of this section except that the following sections in parts 600 through 680 of this chapter shall not be applicable to such products: §§ 600.10(b) and (c), 600.11, 600.12, 600.13, 610.11, 610.53, and 610.62 of this chapter.

(2) To the extent that the requirements in this paragraph (c) conflict with other requirements in this subchapter (except for those products described in paragraph (b) of this section for which a new drug application is required), this paragraph (c) shall supersede other requirements.

(d) Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products. Applicable requirements for the maintenance of establishments for the manufacture of a product subject to this section shall include but not be limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820 of this chapter.

(e) Any establishment and product license for a biological product issued under section 351 of the Public Health Service Act (42 U.S.C. 201 *et seq.*) that has not been revoked or suspended as of December 20, 1999, shall constitute an approved biologics license application in effect under the same terms and conditions set forth in such product license and such portions of the establishment license relating to such product.

**§ 601.3 [Removed]**

35. Section 601.3 *License forms* is removed.

36. Section 601.4 is amended by revising paragraph (a) and the first sentence of paragraph (b) to read as follows:

**§ 601.4 Issuance and denial of license.**

(a) A biologics license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research that the establishment(s) and the product meet the applicable requirements established in this chapter. A biologics license shall be valid until suspended or revoked.

(b) If the Commissioner determines that the establishment or product does not meet the requirements established

in this chapter, the biologics license application shall be denied and the applicant shall be informed of the grounds for, and of an opportunity for a hearing on, the decision. \* \* \*

37. Section 601.5 is revised to read as follows:

**§ 601.5 Revocation of license.**

(a) A biologics license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products manufactured under such license or to discontinue the manufacture of a particular product for which a license is held and waiving an opportunity for a hearing on the matter.

(b)(1) The Commissioner shall notify the licensed manufacturer of the intention to revoke the biologics license, setting forth the grounds for, and offering an opportunity for a hearing on the proposed revocation if the Commissioner finds any of the following:

(i) Authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter,

(ii) Manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made,

(iii) The manufacturer has failed to report a change as required by § 601.12 of this chapter,

(iv) The establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product,

(v) The establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the requirements established in this chapter in order to protect the public health, or

(vi) The licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use.

(2) Except as provided in § 601.6 of this chapter, or in cases involving willfulness, the notification required in this paragraph shall provide a reasonable period for the licensed manufacturer to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for the revocation of the license. If compliance is not

demonstrated or achieved and the licensed manufacturer does not waive the opportunity for a hearing, the Commissioner shall issue a notice of opportunity for hearing on the matter under § 12.21(b) of this chapter.

38. Section 601.6 is revised to read as follows:

**§ 601.6 Suspension of license.**

(a) Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, the Commissioner may notify the licensed manufacturer that the biologics license is suspended and require that the licensed manufacturer do the following:

(1) Notify the selling agents and distributors to whom such product or products have been delivered of such suspension, and

(2) Furnish to the Director, Center for Biologics Evaluation and Research, complete records of such deliveries and notice of suspension.

(b) Upon suspension of a license, the Commissioner shall either:

(1) Proceed under the provisions of § 601.5(b) of this chapter to revoke the license, or

(2) If the licensed manufacturer agrees, hold revocation in abeyance pending resolution of the matters involved.

39. Section 601.9 is revised to read as follows:

**§ 601.9 Licenses; reissuance.**

(a) *Compliance with requirements.* A biologics license, previously suspended or revoked, may be reissued or reinstated upon a showing of compliance with requirements and upon such inspection and examination as may be considered necessary by the Director, Center for Biologics Evaluation and Research.

(b) *Exclusion of noncomplying location.* A biologics license, excluding a location or locations that fail to comply with the requirements in this chapter, may be issued without further application and concurrently with the suspension or revocation of the license for noncompliance at the excluded location or locations.

(c) *Exclusion of noncomplying product(s).* In the case of multiple products included under a single biologics license application, a biologics license may be issued, excluding the noncompliant product(s), without further application and concurrently with the suspension or revocation of the biologics license for a noncompliant product(s).

**§ 601.10 [Removed]**

40. Section 601.10 *Establishment licenses; issuance and conditions* is removed.

41. Section 601.20 is revised to read as follows:

**§ 601.20 Biologics licenses; issuance and conditions.**

(a) *Examination—compliance with requirements.* A biologics license application shall be approved only upon examination of the product and upon a determination that the product complies with the standards established in the biologics license application and the requirements prescribed in the regulations in this chapter including but not limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820 of this chapter.

(b) *Availability of product.* No biologics license shall be issued unless:

(1) The product intended for introduction into interstate commerce is available for examination, and

(2) Such product is available for inspection during all phases of manufacture.

(c) *Manufacturing process—impairment of assurances.* No product shall be licensed if any part of the process of or relating to the manufacture of such product, in the judgment of the Director, Center for Biologics Evaluation and Research, would impair the assurances of continued safety, purity, and potency as provided by the regulations contained in this chapter.

(d) *Inspection—compliance with requirements.* A biologics license shall be issued or a biologics license application approved only after inspection of the establishment(s) listed in the biologics license application and upon a determination that the establishment(s) complies with the standards established in the biologics license application and the requirements prescribed in applicable regulations.

(e) *One biologics license to cover all locations.* One biologics license shall be issued to cover all locations meeting the establishment standards identified in the approved biologics license application and each location shall be subject to inspection by FDA officials.

42. Section 601.21 is revised to read as follows:

**§ 601.21 Products under development.**

A biological product undergoing development, but not yet ready for a biologics license, may be shipped or otherwise delivered from one State or possession into another State or possession provided such shipment or

delivery is not for introduction or delivery for introduction into interstate commerce, except as provided in sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations thereunder (21 CFR parts 312 and 812).

43. Section 601.22 is amended by revising the section heading and the first and second sentences to read as follows:

**§ 601.22 Products in short supply; initial manufacturing at other than licensed location.**

A biologics license issued to a manufacturer and covering all locations of manufacture shall authorize persons other than such manufacturer to conduct at places other than such locations the initial, and partial manufacturing of a product for shipment solely to such manufacturer only to the extent that the names of such persons and places are registered with the Commissioner of Food and Drugs and it is found upon application of such manufacturer, that the product is in short supply due either to the peculiar growth requirements of the organism involved or to the scarcity of the animal required for manufacturing purposes, and such manufacturer has established with respect to such persons and places such procedures, inspections, tests or other arrangements as will ensure full compliance with the applicable regulations of this subchapter related to continued safety, purity, and potency. Such persons and places shall be subject to all regulations of this subchapter except §§ 601.2 to 601.6, 601.9, 601.10, 601.20, 601.21 to 601.33, and 610.60 to 610.65 of this chapter. \* \* \*

44. Section 601.25 is amended in paragraph (b)(3) under "Biological Products Review Information" by revising section VIII and by revising the third sentence of paragraph (f)(3) to read as follows:

**§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.**

\* \* \* \* \*

(b) \* \* \*

(3) \* \* \*

**BIOLOGICAL PRODUCTS REVIEW INFORMATION**

\* \* \* \* \*

VIII. If the submission is by a licensed manufacturer, a statement signed by the authorized official of the licensed manufacturer shall be included, stating that to the best of his or her knowledge and belief, it includes all information, favorable and unfavorable, pertinent to an evaluation of the safety, effectiveness, and labeling of the

product, including information derived from investigation, commercial marketing, or published literature. If the submission is by an interested person other than a licensed manufacturer, a statement signed by the person responsible for such submission shall be included, stating that to the best of his knowledge and belief, it fairly reflects a balance of all the available information, favorable and unfavorable available to him, pertinent to an evaluation of the safety, effectiveness, and labeling of the product.

\* \* \* \* \*

(f) \* \* \*

(3) \* \* \* Where the Commissioner determines that the potential benefits outweigh the potential risks, the proposed order shall provide that the biologics license for any biological product, falling within this paragraph, will not be revoked but will remain in effect on an interim basis while the data necessary to support its continued marketing are being obtained for evaluation by the Food and Drug Administration. \* \* \*

\* \* \* \* \*

45. Section 601.26 is amended by revising the second sentence of the introductory text of paragraph (e), the first, fifth, and sixth sentences of paragraph (f)(1), the second sentence of paragraph (f)(2), and the first sentence of paragraph (f)(3) to read as follows:

**§ 601.26 Reclassification procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.**

\* \* \* \* \*

(e) \* \* \* Where the Commissioner determines that there is a compelling medical need and no suitable alternative therapeutic, prophylactic, or diagnostic agent for any biological product that is available in sufficient quantities to meet current medical needs, the final order shall provide that the biologics license application for that biological product will not be revoked, but will remain in effect on an interim basis while the data necessary to support its continued marketing are being obtained for evaluation by the Food and Drug Administration. \* \* \*

(f) *Additional studies and labeling.* (1) Within 60 days following publication of the final order, each licensed manufacturer for a biological product designated as requiring further study to justify continued marketing on an interim basis, under paragraph (e) of this section, shall submit to the Commissioner a written statement intended to show that studies adequate and appropriate to resolve the questions raised about the product have been undertaken. \* \* \* The Commissioner may extend this 60-day period if

necessary, either to review and act on proposed protocols or upon indication from the licensed manufacturer that the studies will commence at a specified reasonable time. If no such commitment is made, or adequate and appropriate studies are not undertaken, the biologics license or licenses shall be revoked.

(2) \* \* \* If the progress report is inadequate or if the Commissioner concludes that the studies are not being pursued promptly and diligently, or if interim results indicate the product is not a medical necessity, the biologics license or licenses shall be revoked.

(3) Promptly upon completion of the studies undertaken on the product, the Commissioner will review all available data and will either retain or revoke the biologics license or licenses involved.

\* \* \* \* \*

46. Section 601.51 is amended by revising the section heading, the first sentence of paragraph (a), and paragraph (b) to read as follows:

**§ 601.51 Confidentiality of data and information in applications for biologics licenses.**

(a) For purposes of this section the biological product file includes all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions. \* \* \*

(b) The existence of a biological product file will not be disclosed by the Food and Drug Administration before a biologics license application has been approved unless it has previously been publicly disclosed or acknowledged. The Director of the Center for Biologics Evaluation and Research will maintain a list available for public disclosure of biological products for which a license application has been approved.

\* \* \* \* \*

**PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS**

47. The authority citation for 21 CFR part 607 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374; 42 U.S.C. 216, 262.

48. Section 607.20 is amended by revising paragraph (b) to read as follows:

**§ 607.20 Who must register and submit a blood product list.**

\* \* \* \* \*

(b) Preparatory to engaging in the manufacture of blood products, owners

or operators of establishments who are submitting a biologics license application to manufacture blood products are required to register before the biologics license application is approved.

\* \* \* \* \*

49. Section 607.21 is amended by revising the second sentence to read as follows:

**§ 607.21 Times for establishment registration and blood product listing.**

\* \* \* If the owner or operator of the establishment has not previously entered into such operation (defined in § 607.3(d) of this chapter) for which a license is required, registration shall follow within 5 days after the submission of a biologics license application in order to manufacture blood products. \* \* \*

**PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS**

50. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

51. Section 610.13 is amended by revising the introductory paragraph and the first sentence of paragraph (a)(1) to read as follows:

**§ 610.13 Purity.**

Products shall be free of extraneous material except that which is unavoidable in the manufacturing process described in the approved biologics license application. In addition, products shall be tested as provided in paragraphs (a) and (b) of this section.

(a)(1) *Test for residual moisture.* Each lot of dried product shall be tested for residual moisture and shall meet and not exceed established limits as specified by an approved method on file in the biologics license application.

\* \* \*

\* \* \* \* \*

52. Section 610.53 is amended by revising paragraph (d) to read as follows:

**§ 610.53 Dating periods for licensed biological products.**

\* \* \* \* \*

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, issued by the Director, Center for Biologics Evaluation and Research.

53. Section 610.63 is revised to read as follows:

**§ 610.63 Divided manufacturing responsibility to be shown.**

If two or more licensed manufacturers participate in the manufacture of a biological product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.

**PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS**

54. The authority citation for 21 CFR part 640 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

55. Section 640.6 is amended by revising the introductory text to read as follows:

**§ 640.6 Modifications of Whole Blood.**

Upon approval by the Director, Center for Biologics Evaluation and Research, of a supplement to the biologics license application for Whole Blood a manufacturer may prepare Whole Blood from which the antihemophilic factor has been removed, provided the Whole Blood meets the applicable requirements of this subchapter and the following conditions are met:

\* \* \* \* \*

56. Section 640.21 is amended by revising paragraph (c) to read as follows:

**§ 640.21 Suitability of donors.**

\* \* \* \* \*

(c) Plateletpheresis donors shall meet criteria for suitability as described in a biologics license application or a supplement to the biologics license application, and must have the written approval of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

57. Section 640.22 is amended by revising paragraph (c) to read as follows:

**§ 640.22 Collection of source material.**

\* \* \* \* \*

(c) If plateletpheresis is used, the procedure for collection shall be as described in a biologics license application or a supplement to a biologics license application, and must have the written approval of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

\* \* \* \* \*

58. Section 640.64 is amended by revising the second sentence of the introductory text of paragraph (c) to read as follows:

**§ 640.64 Collection of blood for Source Plasma.**

\* \* \* \* \*

(c) \* \* \* One of the following formulas shall be used in the indicated volumes, except that a different formula may be used for plasma for manufacture into noninjectable products if prior written approval is obtained from the Director of the Center for Biologics Evaluation and Research at the time of licensing or in the form of a supplement to the biologics license application for Source Plasma.

\* \* \* \* \*

59. Section 640.65 is amended by revising the last sentence of paragraph (a) to read as follows:

**§ 640.65 Plasmapheresis.**

(a) \* \* \* This procedure shall be described in detail in the biologics license application.

\* \* \* \* \*

60. Section 640.71 is amended by revising the introductory text of paragraphs (a) and (b) and by revising paragraph (b)(1) to read as follows:

**§ 640.71 Manufacturing responsibility.**

(a) All steps in the manufacture of Source Plasma, including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by personnel of the licensed manufacturer of the Source Plasma, except that the following tests may be performed by personnel of a manufacturer licensed for blood or blood derivatives under section 351(a) of the Public Health Service Act, or by a clinical laboratory that meets the standards of the Clinical Laboratories Improvement Act of 1967 (CLIA) (42 U.S.C. 263a): *Provided*, The establishment or the clinical laboratory is qualified to perform the assigned test(s).

\* \* \* \* \*

(b) Such testing shall not be considered divided manufacturing, which requires two biologics licenses for Source Plasma: *Provided*, That

(1) The results of such tests are maintained by the licensed manufacturer of the Source Plasma whereby such results may be reviewed by a licensed physician as required in § 640.65(b)(2) of this chapter and by an authorized representative of the Food and Drug Administration.

\* \* \* \* \*

61. Section 640.74 is amended by revising paragraph (a) and the last sentence of paragraph (b)(2) to read as follows:

**§ 640.74 Modification of Source Plasma.**

(a) Upon approval by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, of a supplement to the biologics license application for Source Plasma, a manufacturer may prepare Source Plasma as a liquid product for a licensed blood derivative manufacturer who has indicated a need for a liquid product.

(b) \* \* \*

(2) \* \* \* Such evidence may be submitted by either the licensed manufacturer of the Source Plasma Liquid or the manufacturer of the final blood derivative product who has requested the Source Plasma Liquid.

\* \* \* \* \*

**PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS**

62. The authority citation for 21 CFR part 660 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

63. Section 660.21 is amended by revising paragraphs (a)(3) and (d) to read as follows:

**§ 660.21 Processing.**

(a) \* \* \*

(3) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a subplot. If lots are to be subdivided, the manufacturer shall include this information in the biologics license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

\* \* \* \* \*

(d) *Volume of final product.* Each manufacturer shall identify the possible final container volumes in the biologics license application.

\* \* \* \* \*

64. Section 660.30 is amended by revising paragraph (b) to read as follows:

**§ 660.30 Reagent Red Blood Cells.**

\* \* \* \* \*

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

65. Section 660.33 is amended by revising the fifth sentence to read as follows:

**§ 660.33 Testing of source material.**

\* \* \* Where fewer than three donor sources of an antibody specificity are available, test discrepancies shall be resolved in accordance with the manufacturer's biologics license application. \* \* \*

Dated: August 30, 1999.

**Jane E. Henney,**

*Commissioner of Food and Drugs.*

**Donna E. Shalala,**

*Secretary of Health and Human Services.*

[FR Doc. 99-27159 Filed 10-19-99; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 25****Environmental Impact Considerations***CFR Correction*

In Title 21 of the Code of Federal Regulations, parts 1 to 99, revised as of Apr. 1, 1999, page 240, § 25.32 is corrected by reinstating text missing from the end of paragraph (i) and the beginning of paragraph (j). In the eighth line of paragraph (i) "percdditive" is corrected to read "percent additive" and the following text is added between the words "percent" and "additive":

**§ 25.32 Foods, food additives, and color additives.**

\* \* \* \* \*

(i) \* \* \* -by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food \* \* \*

\* \* \* \* \*

[FR Doc. 99-55537 Filed 10-19-99; 8:45 am]

BILLING CODE 1505-01-D

**DEPARTMENT OF THE INTERIOR****Minerals Management Service****30 CFR Parts 202 and 206****RIN 1010-AB57****Training Sessions on Gas Valuation for Indian Leases**

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of training sessions.

**SUMMARY:** The Minerals Management Service is offering six training sessions

on our revised Indian gas valuation regulations that are effective January 1, 2000.

**DATES:** See **SUPPLEMENTARY INFORMATION** section for meeting dates.

**ADDRESSES:** See **SUPPLEMENTARY INFORMATION** section for meeting addresses.

**FOR FURTHER INFORMATION CONTACT:** Ms. Vicki Skinner, Royalty Valuation Division, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3152, Denver, CO 80225-0165; telephone number (303) 275-7241, fax number (303) 275-7227.

**SUPPLEMENTARY INFORMATION:** The dates and locations of the training sessions are as follows:

1. *Oklahoma City, OK:* November 1, 1999, 9 a.m. to 4 p.m., Central time. Clarion Airport West Hotel, 737 S. Meridian, Oklahoma City, OK 73108; telephone number (405) 942-8511.

2. *Tulsa, OK:* November 3, 1999, 9 a.m. to 4 p.m., Central time. Radisson Inn, 2201 N. 77th East Ave., Tulsa, OK 74115; telephone number (918) 835-9911.

3. *Farmington, NM:* November 16, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 600 E. Broadway, Farmington, NM 87401; telephone number (505) 327-9811.

4. *Houston, TX:* November 30, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Hotel, 9090 Southwest Freeway, Houston, TX 77074; telephone number (713) 995-0123.

5. *Dallas, TX:* December 6, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Market, 2727 Stemmons Freeway, Dallas, TX 75207; telephone number (214) 630-5332.

6. *Denver, CO:* December 15, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 14707 W. Colfax Ave., Golden, CO 80401; telephone number (303) 279-7611.

MMS published revised Indian gas valuation regulations in the **Federal Register** on August 10, 1999 (64 FR 43506). The revised regulations add alternative valuation methods to existing regulations to ensure that Indian lessors receive maximum revenues from their mineral resources as required by the unique terms of Indian leases and MMS's trust responsibility to Indian lessors. The revised regulations will also improve the accuracy of royalty payments at the time royalties are due.

If you produce gas from Indian lands, the new regulations affect you, and we strongly encourage you to attend one of these training sessions. Some of the topics that will be covered include:



- How do you value gas in an index zone using the index-based formula?
- How do you value gas not in an index zone?
- How do you make a dual accounting election?
- What are the changes to transportation and processing allowances?

MMS is offering these training sessions at no cost to oil and gas industry representatives and members of the public who have an interest in the valuation of gas produced from Indian lands. You must make your own travel and hotel reservations for the training. MMS will not reserve blocks of rooms.

If you plan to attend training, please register for the session by calling or sending a fax to Vicki Skinner at the telephone or fax numbers in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Seating is limited, and we need to know the number in your party.

**Joan Killgore,**

*Acting Associate Director for Royalty Management.*

[FR Doc. 99-27311 Filed 10-19-99; 8:45 am]

BILLING CODE 4310-MR-P

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### 36 CFR Part 13

RIN 1024-AB99

#### Glacier Bay National Park, AK; Commercial Fishing Regulations

**AGENCY:** National Park Service (NPS), Interior.

**ACTION:** Final rule.

**SUMMARY:** This final rule represents a major step towards a comprehensive resolution of commercial fishing issues in Glacier Bay National Park. In accordance with the provisions of Section 123 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (Section 123), as amended, the rule establishes special regulations for commercial fishing in the marine waters of Glacier Bay National Park. The rule implements provisions in Section 123 by: closing specifically identified areas of non-wilderness waters in Glacier Bay proper and all wilderness waters within Glacier Bay National Park to commercial fishing; limiting commercial fishing in Glacier Bay proper to three specific commercial fisheries; establishing a "grandfathering" process to allow qualifying fishermen in the three authorized commercial fisheries to continue fishing in the remaining waters

of Glacier Bay proper under nontransferable lifetime permits; and, clarifying that the marine waters of Glacier Bay National Park outside of Glacier Bay proper will remain open to various existing commercial fisheries. Section 123 also directs that authorized commercial fisheries be managed in accordance with a cooperatively developed state/federal fisheries management plan. The cooperative state/federal fisheries management plan is being developed independent of this rule and will be announced at a later date.

**DATES:** This rule is effective on October 20, 1999, with the exception of paragraphs (a)(10)(i)-(iii) which take effect on January 1, 2000.

**ADDRESSES:** Tomie Lee, Superintendent, Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, Alaska 99826.

E-mail address is *glba-administration@nps.gov*.

**FOR FURTHER INFORMATION CONTACT:**

Tomie Lee, Superintendent, Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, Alaska, 99827, Phone (907) 697-2230; fax (907) 697-2654.

**SUPPLEMENTARY INFORMATION:**

#### Background

The background section in the re-proposed rule of August 2, 1999 (64 FR 41854), includes a comprehensive chronology of Glacier Bay's commercial fishing history that outlines the circumstances and events leading to this final rule. That information is unchanged and has continuing applicability. The National Park Service (NPS) wishes to note that numerous extensions to the public comment period on the 1997 proposed rule afforded the public a prior opportunity to comment on Section 123 (see *e.g.*, 63 FR 68655, December 11, 1998; 64 FR 1573, January 11, 1999). The re-proposed rule was published, in part, to fulfill the requirement of Section 123, as amended by Pub. L. 106-31 (May 21, 1999), which directed the Secretary of the Interior to re-publish the rule and provide an opportunity for the public to comment for not less than 45 days.

To comply with Section 123, the rule, in part, amends the general regulatory prohibition on commercial fishing activities in units of the National Park System, and authorizes various existing commercial fisheries to continue in most marine waters of Glacier Bay National Park subject to a cooperatively developed state/federal fisheries management plan.

The other provisions of the rule also conform to the requirements of Section 123. The rule limits commercial

fisheries in Glacier Bay proper to pot and ring net fishing for Tanner crab, longlining for halibut, and trolling for salmon. The rule describes eligibility criteria that allow certain fishermen with a sufficient, recent, reoccurring history of participation in Glacier Bay proper fisheries to continue fishing in Glacier Bay proper for their lifetimes. The final rule adopts October 1, 2000, as the deadline to apply for a lifetime permit. Beginning October 1, 2000, a lifetime permit is needed in order to fish in Glacier Bay proper. To qualify, fishermen must be able to document that they have fished in Glacier Bay proper in one of the three authorized commercial fisheries as follows: For the halibut fishery, 2 years of participation are required in Glacier Bay proper during the 7-year period, 1992 through 1998. For the salmon and Tanner crab fisheries, 3 years of participation are required in Glacier Bay proper during the 10-year period, 1989 through 1998. The 7-year qualifying period for halibut is based, in large part, on the establishment of a statistical sub-area for Glacier Bay proper in 1992. Use of this qualifying period specific to this sub-area will assist fishermen in documenting, and NPS in identifying, a history of fishing within Glacier Bay proper. A 10-year qualifying period is used for the Tanner crab and salmon fisheries. These qualifying periods (of 7 and 10 years, respectively) are intended to provide a better opportunity for fishermen with a variable but reoccurring history of participation in these fisheries, in Glacier Bay proper, to qualify for the lifetime access permits. Essentially, these criteria require fishermen to have fished in Glacier Bay proper for approximately 30% of the years during the 7 and 10-year base periods to qualify for lifetime access to an authorized fishery.

The rule also describes the application requirements and procedures for fishermen to follow to apply for a lifetime access permit for an authorized fishery in Glacier Bay proper. The rule requires that applicants: demonstrate that they hold a valid state limited entry commercial fishing permit, and for halibut an International Pacific Halibut Commission quota share, for the fishery in Glacier Bay proper; provide a sworn and notarized affidavit attesting to their history and participation in the fishery within Glacier Bay proper; and, provide other documentation that corroborates their participation in the fishery in Glacier Bay proper during the qualifying years. The rule requires applicants to



provide two types of corroborating documentation readily available from the State of Alaska: permit histories; and, landing reports. The permit history documents the length of time an applicant has been a permit holder in a fishery, and the landing report documents the time and location of the applicant's fishery landings. The application requirements for a lifetime commercial fishing access permit in Glacier Bay (*i.e.*, a copy of the valid permit(s) and quota share(s), affidavit, permit history and landing report) are less demanding than that typically required by the State of Alaska or National Marine Fisheries Service (for halibut) for similar limited entry programs. The rule encourages applicants to submit other forms of corroborating documentation—for example, vessel logbooks or affidavits from other fishermen or processors—to assist in the establishment of their history of participation in a particular fishery in Glacier Bay proper.

NPS recognizes the limitations of landing report data based on fish tickets. Although Alaska statute requires accurate reporting of fish harvest information by statistical area, fishermen often lump together catches from Glacier Bay proper and Icy Strait statistical areas, and report them as Icy Strait landings on their fish tickets. Moreover, no statistical reporting area exists for salmon that is specific to Glacier Bay proper. Because of this, for the salmon fishery, NPS will consider landing reports from District 114 (all of Icy Strait from Cross Sound to the Lynn Canal, including Glacier, Dundas and Taylor Bays and Excursion Inlet) as indirect evidence of participation in the fishery in Glacier Bay proper; this indirect evidence, however, must be supported by additional documentation that supports applicants' declaration of Glacier Bay proper salmon landings (such as affidavits from crewmembers, other fishermen, processors or logbooks or other corroborating documentation). Salmon fishermen who can document more than incidental use of District 114 should submit that documentation as it may bolster other evidence of their landings from the Glacier Bay proper fishery.

Both the halibut fishery (Regulatory Sub-area 184) and the Tanner crab fishery (Statistical areas 114–70 through 114–77) have reporting areas specific to Glacier Bay proper. Therefore, applicants who wish to rely on landing data from areas outside, but immediately adjacent to, Glacier Bay proper must submit convincing corroborating documentation (such as affidavits from crewmembers, other

fishermen, processors or log books) in addition to their personal affidavit that a portion of their catch was landed in Glacier Bay proper. Landing reports for halibut and Tanner crab must, at the very least, be from the reporting area immediately adjacent to Glacier Bay proper to be considered. In the case of halibut, this is Regulatory Sub-area 182; in the case of Tanner crab, this is Statistical area 114–23. These requirements are intended to address concerns regarding the difficulty of attributing harvest to Glacier Bay proper from landing reports, most particularly for the salmon troll fishery. NPS intends to work closely with the Alaska Commercial Fisheries Entry Commission, the National Marine Fisheries Service and other knowledgeable sources to identify permit owners who meet the eligibility criteria defined for the authorized commercial fisheries in Glacier Bay proper.

The rule also closes certain inlets and areas, in the upper reaches of Glacier Bay proper, to commercial fishing and limits certain other areas to winter season trolling for king salmon by qualifying fishermen. There are a number of species-specific closure dates in Section 123, and the effective date of paragraph (a)(10)(i)–(iii) is delayed until January 1, 2000, to comply with the statute. The rule reaffirms closure of all designated wilderness areas in Glacier Bay National Park to commercial fishing activities.

By authorizing existing commercial fisheries to continue in park waters outside of Glacier Bay proper, Section 123 and the rule permit fishing to continue where more than 80% of the commercial harvest (reported biomass) has historically occurred. Additional harvest will continue in most of Glacier Bay proper during the life tenancy period of qualifying fishermen, supporting fishermen and their communities for many years. Approximately 18% of the park's marine waters are closed to commercial fishing by Section 123 and this rule; these closed waters have historically accounted for less than 10% of the total commercial harvest in the park. Nothing in the rule is intended to modify or restrict non-commercial fishing activities otherwise authorized under federal and non-conflicting state fishing regulations, nor to affect legislatively authorized commercial fishing activities within Glacier Bay National Preserve.

#### **Analysis of Public Comments**

Due to the enactment of Section 123 (on October 21, 1998), NPS reopened and extended the comment period on

the 1997 proposed rule and the accompanying Environmental Assessment (63 FR 68665, December 11, 1998; 64 FR 1573, January 11, 1999). NPS also mailed a copy of the **Federal Register** Notice of extension to persons and organizations that had previously submitted comments and invited them to provide additional comments in light of the new legislation. The analysis of public comment section in the re-proposed rule of August 2, 1999 (64 FR 41854), includes a comprehensive analysis of 1,557 comments submitted in response to the proposed rule and the enactment of Section 123. That information has continuing applicability and supplements this analysis.

#### **Overview of Public Comments**

The public comment period on the re-proposed rule for commercial fishing in Glacier Bay National Park was open from August 2 to September 16, 1999, and specifically sought input on the re-proposed eligibility criteria and application requirements for lifetime permits for authorized fisheries in Glacier Bay proper. NPS received 96 written comments, in the form of surface mail, faxes and electronic mail. NPS reviewed and considered all public comments submitted on the re-proposed rule. A summary of substantive comments is outlined below.

Thirty-seven percent of the comments received specifically stated support for some form of commercial fishing phase out in Glacier Bay National Park. Twenty-two percent specifically stated support for the continuation of commercial fishing.

Of all the responses received, 59% specifically commented on the eligibility criteria for commercial fishing lifetime access permits. Among those, more than half (54%) supported less stringent eligibility criteria than that stated in the re-proposed rule. The remaining comments on eligibility (46%) supported the eligibility criteria as a minimum standard, including 30% who sought more stringent eligibility criteria. Comments ranged from suggestions for more relaxed criteria for lifetime permits, such as one year of fishing during the eligibility period, to calls for the stronger criteria as proposed in 1997.

Twenty-two percent of all respondents commented specifically on the application process for commercial fishing lifetime access permits. Of those, 67% supported a less stringent process than that stated in the re-proposed rule. Thirty-four percent supported the process, as the minimum standard that the NPS should set for application

approval, 20% of which sought a more stringent process.

#### *General Comments*

Collectively, there were a number of comments and objections concerning various parts of the rule that, in fact, are derived directly from the statute. For example, a number of commenters requested that public comment be extended. Section 123 established a publication date of September 30, 1999, and NPS has used its best efforts to publish on that date; that necessarily affects the timing and length of the latest public comment period. It should also be noted that NPS has been actively seeking public comment for several years (as summarized at 64 FR 41856-8, August 2, 1999). Section 123 also requires that a "sworn and notarized affidavit be submitted," not just licenses and fish tickets (landing receipts). Section 123 authorized lifetime permits for those holding "a valid commercial fishing permit" who otherwise qualify, not boat owners or deckhands. On this point, however, NPS notes that Section 123, as amended, provides \$23 million to compensate "fish processors, fishing vessel crewmembers, communities and others negatively affected by the restrictions on commercial fishing in Glacier Bay National Park." One commenter (who will certainly qualify for a lifetime permit) felt he was "singled-out" because, unlike most other limited entry permit holders, he likes to longline in the west arm of the bay above 58°50' N latitude. Numerous commenters stated that commercial fishing was inappropriate in Glacier Bay and other national parks. NPS has considered these comments, but NPS must follow the statute. NPS also received many comments on related subjects that were, however, outside of the limited scope of this rule.

#### *Regulatory Flexibility Analysis*

NPS received a number of comments on the initial regulatory flexibility analysis. Those comments are discussed below in the summary of the final regulatory flexibility analysis that NPS has prepared as required by 5 U.S.C. 604.

#### *Rationale for the Qualifying Period*

A number of commenters questioned whether NPS had done enough to explain the method used to determine the necessary number of years in a given base year period to qualify for lifetime access to fish under the rule. One commenter felt that the NPS effort to "mirror similar lengths of time that have been allowed in other state and federal limited entry programs" was misplaced

because "those programs were influenced by conservation concerns." Other commenters, however, cited conservation concerns and the Glacier Bay 1996 Vessel Management Plan regulations which limits the amount of motor vessel traffic allocated to park visitors (61 FR 27008, May 30, 1996), to push for a shorter, more stringent phase out of commercial fishing. In the 1997 proposed rule, NPS proposed a longer history of participation in each fishery to prevent what the Wilderness Society now critically points out is possible: that people who started fishing after the 1991 rulemaking proposed to phase out all commercial fishing in seven years would be eligible for grandfather status to fish in Glacier Bay. However, even in that proposal, NPS recognized the need for some flexibility to ensure fairness to fishermen with a variable but recurring history of participation in Glacier Bay fisheries. Ultimately, and with public comment sharply divided, NPS selected shorter requirements for participation in the fishery in the qualifying base year periods (3 years in a 10-year base for salmon and Tanner crab fisheries, and 2 years in a 7-year base for halibut fisheries) to meet that objective. As a result, fishermen are required to show they have fished in Glacier Bay proper for approximately 30% of the years during the 7 and 10-year base periods to qualify. Resolving the commercial fishing issue in Glacier Bay has been a long and contentious process (see 64 FR 41856-9, August 2, 1999). Section 123 now directs NPS to decide who qualifies for lifetime access and who does not; NPS has drawn the line where it thinks it is fair, recognizing that it will not please everyone.

#### *Cooperative Development of the Management Plan*

Several commenters questioned the role that NPS and the State of Alaska will play in the cooperatively developed management plan required by Section 123. The plan will guide the regulation of the existing authorized fisheries at Glacier Bay National Park. One commenter stated that it was an "oversimplification" for NPS to state that the State manages fisheries to maintain sustained yield. In response, NPS notes that the Alaska State Constitution states: "Fish \* \* \* and all other replenishable resources belonging to the State shall be utilized, developed, and maintained on the sustained yield principal, subject to preference among beneficial uses." *Id.* at Article VIII, Section 4. Another commenter questioned what NPS considers as park values and purposes, and many commenters questioned how NPS

would protect the park's resources. After reviewing the re-proposed rule, NPS agrees that some clarification is necessary. Section 123 clearly states: "the management plan shall provide for commercial fishing in the marine waters within Glacier Bay National Park \* \* \* and shall provide for the protection of park values and purposes. \* \* \*" *Id.* Park values and purposes are identified in 16 U.S.C. 1, as amended, and are further defined by the enabling legislation and legislative history of Glacier Bay National Park. As a result, the cooperatively developed management plan must consider and respect the NPS mission in Glacier Bay National Park as defined and directed by Congress.

Section 123 also requires the management plan to prohibit any new or expanded fisheries, and provide for the opportunity for the study of marine resources. Therefore, a legislatively-mandated component of the cooperative management plan is the accommodation of scientific study. Section 123 does not require that all federal and federally-approved research within the park fall under the plan. The final rule also contains a provision that directs the superintendent to compile a list of existing fisheries and gear types used in the outer waters. NPS will work with the State, outer water fishermen and the public to cooperatively develop this list. However, should new or expanded fishing activities threaten park resources during development of the cooperative plan, the superintendent may implement an interim list.

Section 123 provides both a requirement and an opportunity for ongoing cooperation and collaboration between the State and federal government in the implementation of a jointly-developed fisheries management plan. NPS will work together with the State to provide the public with an opportunity to participate in the development of the cooperative management plan, independent of this rulemaking. NPS believes that the best long-term remedy for this jurisdictional issue is an effective State/federal cooperative relationship that: outlines and respects individual and collective agency roles and responsibilities; keeps lines of communication open; incorporates opportunities for public involvement in decision-making processes; and, ultimately, serves to implement the letter and spirit of the Section 123, as amended. NPS intends to devote its energies towards this goal.

*1996 Vessel Management Plan (VMP) Regulations*

A comment received from the Alaska Chapter of the Sierra Club stated that commercial fishing boats are not subject to the 1996 VMP regulations (36 CFR 13.65(b)). This assertion, however, is only partially correct; generally the VMP regulations apply to commercial fishing vessels. While commercial fishing vessels were exempted from the entry permit requirements of that rule by § 13.65(b)(2)(iii)(D), this rule will require such boats to obtain a National Park Service permit to enter the bay, from June 1 through August 31. The Sierra Club comment correctly pointed out that commercial fishing vessels were exempted from the restriction on operating within one-quarter nautical mile of a whale (§ 13.65(b)(3)(i)). This exemption was made due to the slow speeds and deliberate courses that commercial fishing vessels follow. However, the whale waters restrictions at § 13.65(b)(iv)(D)(1) apply unless a motor vessel (commercial or sport) is actually fishing (and not simply in transit). Seasonal motor vessel closures are specifically applicable (61 FR 27008, 27013, May 30, 1996).

NPS also notes that, regardless of whether an commercial fishing vessel operator possesses a commercial fishing lifetime access permit, the operator of a commercial fishing vessel can apply for a private vessel permit to enter Glacier Bay from June 1 through August 31, or visit Glacier Bay during the balance of the year, provided they follow the regulations that apply to private motor vessels and do not engage in commercial activities. Lifetime permittees are advised that the lifetime permit only allows access for commercial fishing; entering the park for other commercial purposes is prohibited, and entering Glacier Bay for recreation purposes (from June 1 through August 31) requires a private vessel permit. Commercial fishing vessels may, at any time, seek safe harbor in Glacier Bay National Park when faced with hazardous weather or sea conditions, mechanical problems, or other exigent circumstances.

*Resource Violations*

One commenter suggested that a commercial fishing lifetime access permit holder who commits a resource violation in the park should have his or her permit revoked. Although NPS believes that most people who will qualify for the permit will respect park resources and regulations, NPS will not hesitate to ask a court to impose access restrictions on a permit holder who is

convicted of serious or repeated offenses. NPS will also seek the State's support in including provisions to this effect in the cooperatively developed management plan. NPS believes that such action would be consistent with Congress' direction that the plan "shall provide for the protection of park values and purposes." Section 123(a)(1).

*Boundaries and Maps*

NPS will provide detailed maps and charts depicting non-wilderness and wilderness closures to every fisherman who receives a commercial fishing lifetime access permit for one of the three authorized Glacier Bay proper commercial fisheries. Others may contact the superintendent for a map of these closures.

*Section by Section Analysis*

The regulations in this section implement the statutory requirements of Section 123 of the Omnibus Emergency and Supplemental Appropriations Act for FY 1999 (Section 123) (Pub. L. 105-277), as amended by Section 501 of the 1999 Emergency Supplemental Appropriations Act (Pub. L. 106-31.) Where possible, the language used in this section of the regulations mirrors the language used in Section 123, as amended.

Section 13.65(a)(1) of the regulations provides definitions for the terms "commercial fishing" and "Glacier Bay" and "outer waters." The definition for "commercial fishing" is the same as used for the park's vessel regulations in § 13.65(b) of Title 36 of the Code of Federal Regulations (36 CFR). The terms "Glacier Bay" and "outer waters" are used in these regulations to describe marine water areas of the park that are to be regulated differently under requirements of Section 123. The definition for "Glacier Bay" mirrors the definition for "Glacier Bay Proper" that is provided in Section 123, and is also essentially the same as the definition used in 36 CFR 13.65(b)(1). The term "outer waters" is used to describe all of the marine waters of the park outside of Glacier Bay proper. This includes areas of Icy Straits, Cross Sound, and coastal areas on the Gulf of Alaska running from Cape Spencer to Sea Otter Creek, beyond Cape Fairweather.

Section 13.65(a)(2) of the regulations provides authorization for commercial fishing to continue in the non-wilderness marine waters of the park, as specifically provided for by Section 123, as amended. In addition to Glacier Bay, park waters that are affected by Section 123 include all of the "outer waters" of the park outside of Glacier Bay. This authorization for commercial fishing

supercedes the general regulatory prohibition on commercial fishing in the park found at 36 CFR 2.3(d)(4). The authorization, however, does not supercede other NPS regulations or exempt commercial fishermen or their vessels from any other generally applicable park regulations. Commercial fishing activities are to be conducted and managed in concert with park purposes and values. Paragraph (i) reflects the Section 123 requirement that the State of Alaska and the Secretary of the Interior cooperatively develop a fisheries management plan to guide the regulation of commercial fisheries in the park that will: reflect the requirements of Section 123, other applicable federal and state laws, and international treaties; serve to protect park values and purposes; prohibit new or expanded commercial fisheries; and, provide opportunity for the study of marine resources. Paragraph (ii) clarifies that waters designated as wilderness are closed to commercial fishing and related commercial activities. Paragraph (iii) has been added to address the Section 123 prohibition on any new or expanded fisheries and provides a mechanism for future implementation of that prohibition. Paragraph (iv) informs the public that maps and charts of the affected waters available from the superintendent.

Section 13.65(a)(3) of the regulation implements Section 123 requirements that the commercial fisheries in Glacier Bay are limited to longlining for halibut, pot or ring net fishing for Tanner crab, and trolling for salmon. These are the only commercial fisheries authorized to continue in Glacier Bay. Paragraph (ii) limits participation in the authorized commercial fisheries in Glacier Bay to individuals who have a non-transferable commercial fishing lifetime access permit issued by the superintendent. The requirement for this lifetime access permit will not go into effect until October 1, 2000. The delayed implementation date (the re-proposed rule would have adopted January 1, 2000, as the implementation date) is intended to allow sufficient time for fishermen to apply for, and receive, their access permits before the permit requirement takes effect. Fishermen are strongly advised to apply well before the October 1, 2000, deadline to ensure that their application is processed and approved by that date. This section also makes clear that the permits are non-transferable—reflecting the language and requirements of Section 123. However, if a temporary emergency transfer of a permit is approved by the Commercial Fisheries Entry

Commission (CFEC) due to illness or disability of a temporary, unexpected and unforeseen nature, NPS will also consider issuing a temporary lifetime access permit transfer for the period (generally, one year or less). In response to public comment, paragraph (iii) has been added to better protect park resources. This paragraph also provides a mechanism for future implementation of the cooperatively developed management plan.

Section 13.65(a)(4) of this regulation restates the Section 123 requirement that an applicant must possess a valid State limited entry commercial fishing permit for the district or statistical area encompassing Glacier Bay, for each fishery for which a lifetime access permit is being sought. Paragraph (ii) outlines the specific eligibility requirements that must be met to obtain a lifetime access permit for an authorized fishery in Glacier Bay. An applicant must have participated as a limited entry permit holder for the minimum number of years in the established base years period, and in the district or statistical area encompassing Glacier Bay, for each authorized fishery, for each fishery for which a lifetime access permit is being sought. These eligibility criteria have undergone a Regulatory Flexibility Act analysis, and have been determined to meet the goals of this regulation, while seeking to minimize impacts to commercial fishermen and other affected small businesses to the extent consistent with Section 123, as amended. A 12-month application period to obtain a lifetime access permit is described; conclusion of the eligibility determinations by October 1, 2000, may be important to ensure completion of the \$23 million compensation program authorized by Congress in the 1999 amendment to Section 123. Section 13.65(a)(5) outlines the specific type of documentation that an applicant must provide to the superintendent to obtain a lifetime access permit. Section 123 requires fishermen to provide a sworn and notarized personal affidavit attesting to their history of participation as a limited entry permit holder within Glacier Bay, during the qualifying period, for each fishery for which a lifetime access permit is being sought. NPS will provide a simple affidavit form to applicants upon request. Section 123 also requires applicants to provide other documentation that corroborates their history of participation in the fishery, and a copy of their current State of Alaska limited entry permit (and in the case of halibut, an International Pacific Halibut Commission quota share) that is

valid for the area that includes Glacier Bay for each fishery for which a lifetime access permit is sought. Licensing and landing histories—two types of readily available corroborating documentation—are required by this regulation. A certified printout of an applicant's licensing history in a fishery is available at no charge from the CFEC. The licensing history corroborates participation in the fishery during the qualifying years. Landing reports, documenting an applicant's harvest activities in a specific commercial fishery by year and location, are available at no charge from the Alaska Department of Fish and Game (ADFG). A form is required from ADFG to obtain this information. NPS is aware of the limitations of some landing data. There is, for example, no separate statistical reporting unit for Glacier Bay for salmon trolling. Accordingly, the superintendent will consider salmon landing reports for District 114 as indirect evidence of participation in the Glacier Bay fishery, provided that such reports are supported by additional corroborating documentation of Glacier Bay landings. For the halibut and Tanner crab fisheries, because specific reporting areas are described for Glacier Bay, the superintendent may consider landing data from a unit or area immediately adjacent to Glacier Bay when additional and convincing corroborating documentation of landings in Glacier Bay is included. Landing reports must be for the reporting area immediately adjacent to Glacier Bay to be considered.

Section 13.65(a)(6) establishes October 1, 2000, as the deadline to apply for a commercial fishing lifetime access permit. This section also publishes the address where applications must be sent. Fishermen are strongly advised to apply well before the October 1, 2000, deadline to ensure their application is processed and approved by that date.

Section 13.65(a)(7) clarifies that the superintendent will make a written determination and provide a copy to the applicant. Applicants will be afforded an opportunity to provide additional information, if it is required. NPS anticipates that it could take 45 days or more to process and respond to an application, depending on the volume and completeness of the applications received. For this reason, applicants are strongly advised to apply well before the October 1, 2000, deadline, or at least 45 days in advance of anticipated fishing activities in Glacier Bay if that date is sooner.

Subsection 13.65(a)(8) describes the appeal procedures for an applicant to

follow if the superintendent finds the applicant to be ineligible. These procedures are similar to those in place for other NPS permit programs in Alaska.

Subsection 13.65(a)(9) makes clear that the lifetime access permits to the Glacier Bay proper commercial fisheries are renewable for the lifetime of an access permit holder, provided they continue to hold a valid commercial fishing permit and are otherwise eligible to participate in the fishery under federal and State laws. NPS expects to reissue the lifetime access permits on a five-year cycle. This will provide an opportunity for NPS to occasionally update the list of fishermen authorized to commercial fish in Glacier Bay. NPS will not charge a fee for these permits. Access permits will not be required for commercial fisheries authorized in the marine waters of the park outside Glacier Bay.

Section 13.65(a)(10), paragraphs (i)–(iii) describe several non-wilderness inlets within Glacier Bay that Section 123 closed to commercial fishing. The 1999 amendments to Section 123 delay implementation of these non-wilderness closures during the 1999 fishing season for the commercial halibut and salmon troll fisheries. The rule, therefore, delays the effective date of these three paragraphs until December 31, 1999, to accommodate the provisions of the Section 123 amendments. Wilderness areas, however, remained closed to all commercial fishing under the 1999 amendments, with no delay in implementation; these closures were put into effect by NPS on June 15, 1999. NPS will provide detailed maps and charts depicting these non-wilderness and wilderness closures to fisherman who receive a lifetime access permit for an authorized Glacier Bay proper commercial fishery. Paragraph (i) implements the closure of Tarr Inlet, Johns Hopkins Inlet, Reid Inlet, and Geike Inlet to all commercial fisheries. These closures include the entirety of each of these inlets, as depicted on the maps and charts available from the superintendent. Paragraph (ii) describes the general closure of the west arm of Glacier Bay to commercial fishing, with the exception of trolling for king salmon by authorized commercial salmon fishermen during the State's winter season troll fishery (as per Section 123). Paragraph (iii) describes the general closure of the east arm of Glacier Bay north of a line drawn across the mouth of the arm from Point Caroline through the southern point of Garforth Island to the east shore mainland, with a similar exception that allows authorized salmon fishermen to troll for king salmon

during the State's winter troll fishery "south of a line drawn across Muir Inlet at the southernmost point of Adams Inlet." Section 123(a)(4). This line is described in this subsection as 58°50'N latitude, a description more readily understood by commercial fishermen.

**Drafting Information:** The primary authors of this rule are Randy King, Chief Ranger, Mary Beth Moss, Chief of Resource Management, and Chad Soiseth, Aquatic Biologist, Glacier Bay National Park and Preserve; and Donald J. Barry, Assistant Secretary of the Interior for Fish and Wildlife and Parks. Other key contributors include Molly Ross, Special Assistant to the Assistant Secretary for Fish and Wildlife and Parks; Marvin Jensen and John Hiscock of the National Park Service. Paul Hunter, National Park Service Alaska Support Office; and Russel J. Wilson, Denali National Park and Preserve also contributed.

The regulatory language of the re-proposed rule has been converted to the question and answer format in accordance with the Department of the Interior, Office of Regulatory Affairs, policy on Plain Language. No substantive changes to the proposed language have been made.

#### Compliance with Other Laws

##### *Regulatory Flexibility Act*

Under the Regulatory Flexibility Act of 1980, as amended, 5 U.S.C. 601 *et seq.*, the NPS has determined that this rule will have a significant impact on a substantial number of small business entities. The NPS has summarized the final regulatory flexibility analysis on the expected impact of this rule on those small business entities as follows.

(1) This Rule is published in accordance with the provisions of Section 123 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (Section 123), as amended. The rule establishes special regulations for commercial fishing in the marine waters of Glacier Bay National Park. The rule implements provisions in Section 123 by:

- Closing specifically identified areas of non-wilderness waters in Glacier Bay proper and all wilderness waters within Glacier Bay National Park to commercial fishing.
- Limiting commercial fishing in Glacier Bay proper to three specific commercial fisheries.
- Establishing a "grandfathering" process to allow qualifying fishermen in the three authorized commercial fisheries to continue fishing in the

remaining waters of Glacier Bay proper under nontransferable lifetime permits.

- Clarifying that the marine waters of Glacier Bay National Park outside of Glacier Bay proper will remain open to various existing commercial fisheries.

(2) The following is a summary of the comments relating to the initial Regulatory Flexibility Analysis and the NPS assessment and response.

Several commenters challenged the NPS analysis of the impact the rule would have on small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). One commentator specifically contended that NPS was incorrect in certifying that the rule did not have a significant economic impact on a substantial number of small entities, and should therefore have conducted the analysis required under the Regulatory Flexibility Act. NPS would like to point out that for the August 2, 1999 re-proposed rule it did not so certify, and that it did conduct the Regulatory Flexibility Analysis required under 5 U.S.C. 601 *et seq.*

Another commenter asked whether NPS took into account the effects which the rule would have on the value of assets, (e.g., vessels, fishing gear, permits). NPS stated in its economic analysis that it did not account for the effect of the rule on assets. NPS believes that any asset effects will be small for two reasons: (1) the market for used equipment is extensive and the effect of fishing restrictions in one venue (Glacier Bay) on market prices is minimal, and (2) there are opportunities for fishermen displaced to replace significant portions of lost revenues in other fishing venues. Further, Congress has appropriated funds to compensate for estimated economic losses. Since NPS and the State of Alaska have not yet developed the decision rules and eligibility criteria for dispensing these funds, the opportunity to identify effects that warrant compensation still exists.

Several commenters argued that the NPS's analysis was flawed, and in particular, that: the analysis did not meet the standards of 5 U.S.C. 601 *et seq.*; NPS did not reveal the details of its study design; and, NPS failed to use the best scientific data available. NPS consulted extensively with staff at the Small Business Administration regarding the design of the study, and was careful to comply with the standards of 5 U.S.C. 601 *et seq.* Although NPS did not publish the State of Alaska's Commercial Fisheries Entry Commission (CFEC) data, nor the individual calculations made therefrom, it fully described the nature of these calculations and published the cumulative results. The NPS also used

the best scientific data available for its analysis.

A few commenters questioned NPS's finding that the rule is not a significant regulatory action for purposes of E.O. 12866 (Regulatory Planning and Review) and 2 U.S.C. 1501 *et seq.* (Unfunded Mandates Reform Act). In response, NPS notes that we have determined that the rule is significant under E.O. 12866 but not under 2 U.S.C. 1501. The NPS estimated that the present value of the income effects of the rule would be less than \$9.2 million. A present value of \$9.2 million is equivalent to \$276,000 annually, assuming a discount rate of 3% in perpetuity, or \$358,000 annually, if the full impact is absorbed over 50 years. NPS used the best scientific data available to arrive at this estimate, and made what it believed to be very conservative assumptions in conducting the analysis. As described in the economic analysis, NPS based its analysis on (1) data collected by the CFEC on harvest sizes and values, location of catch, and permittee participation by venue and (2) two studies conducted by Dr. Jeff Hartman, Alaska Department of Fish and Game. NPS has confidence in Dr. Hartman's analysis; it was carefully designed and executed and formed the basis of Congress's \$23 million appropriation for compensation.

No changes were made in the Final Rule as a result of the public comment detailed above. NPS notes, however, that the eligibility criteria adopted by this rule (as proposed in the re-proposed rule) are less stringent than the criteria originally proposed in the 1997 proposed rule. NPS chose the less stringent criteria because public comment and the initial regulatory flexibility analysis led NPS to conclude that the more stringent criteria would have adversely affected the economic well being of an unacceptably high number of fishermen as well as local communities.

(3) The rule will apply primarily to current holders of a valid limited-entry, commercial fishery permit for Tanner crab, halibut, and/or salmon troll fisheries that have fished within Glacier Bay proper or adjacent areas over the ten year period 1989–98. Because some permit holders may hold permits for multiple fisheries and because statistical reporting units for which permit holders report their catch align poorly with park boundaries or have changed configuration over time it is extremely difficult to estimate the number of permit holders impacted by the rule (*i.e.*, those displaced by, or not qualifying to continue fishing under, the

rule). Our best estimates, obtained from the CFEC, indicate that 40–50 Tanner crabbers, 80–220 halibut fishermen, 80–330 hand trollers and 100–380 power trollers would be displaced from Glacier Bay proper. Estimates for salmon trollers encompass both summer and winter fisheries openings for Statistical Area 114, which includes Cross Sound and Icy Strait in addition to Glacier Bay proper. The troll fishery in the Bay proper typically occurs during the winter opening and the number of affected entities is most likely closer to the lower estimate for this fishery. Other small entities which are likely to be affected by this final rule include: vessel owners who are not permit holders, crew members, seafood processing firms, seafood processing laborers, lost tax revenues to local government jurisdictions, and fishing support sector small entities in local communities (*i.e.*, chandlerys, fishing gear and hardware stores, fuel sales, grocery stores, boat mechanics, etc.). Fewer than 40 vessel owners who are not permit holders are currently estimated to be affected by this final rule, although the number of vessels that will continue to be leased by qualifying permit holders and will continue to participate in Glacier Bay proper fisheries is unknown. It is currently not possible to estimate the number of small entities in these other classes because many of the spatial and temporal parameters of projected affects are currently not well known.

(4) The projected reporting, record keeping and other compliance requirements are described in the rule. Section 13.65(a)(5) outlines the specific type of documentation that an applicant must provide to the superintendent to obtain a lifetime access permit. Section 123 requires fishermen to provide a sworn and notarized personal affidavit attesting to their history of participation as a limited permit holder within Glacier Bay, during the qualifying period, for each fishery for which a lifetime access permit is being sought. Section 123 also requires applicants to provide other documentation that corroborates their history of participation in the fishery, and a copy of their current State of Alaska limited entry permit (and in the case of halibut, an International Pacific Halibut Commission quota share) that is valid for the area that includes Glacier Bay for each fishery for which a lifetime access permit is sought. Licensing and landing histories—two types of readily available corroborating documentation—are required by this regulation. A certified printout of an applicant's licensing history in a fishery is available at no

charge from the CFEC. The licensing history corroborates participation in the fishery during the qualifying years. Landing reports, documenting an applicant's harvest activities in a specific commercial fishery by year and location, are available at no charge from the Alaska Department of Fish and Game (ADFG).

The classes of small entities which will be subject to the requirement are current limited entry permit holders for the Glacier Bay commercial halibut fishery who have participated as a permit holder in that fishery for at least two years during the period 1992–1998, and current limited entry permit holders for the Glacier Bay salmon or Tanner crab commercial fisheries who have participated as a permit holder in that fishery for at least three years during the period 1989–1998. No professional skills are necessary for preparation of the report or record. All necessary materials are available either from ADFG or the CFEC.

(5) NPS has and will continue to mitigate the significant economic impact on small entities impacted by this statute by the following actions:

- This rule adopts October 1, 2000 as the effective date of the Glacier Bay proper permit requirement, rather than the re-proposed rule date of January 1, 2000 to give applicants more time to collect the required documentation and apply for the permit.
- This rule selected the less stringent eligibility criteria for lifetime permits that was published in the re-proposed rule (two years in seven, and three years in ten) rather than the eligibility criteria that was originally proposed (six years in ten).
- NPS will administer, in a fair and timely manner, the mandated 23 million dollar compensation program, which will recompense small entities affected by the phase-out of commercial fishing in specified areas of Glacier Bay National Park.

Most aspects of the rule are direct requirements of Section 123. Section 123 also directed the Secretary of the Interior to determine the eligibility criteria for the Glacier Bay fishery. The eligibility criteria adopted by this rule (as proposed in the re-proposed rule) is less stringent than the criteria originally proposed in the 1997 proposed rule. NPS chose the less stringent criteria because public comment and the initial regulatory flexibility analysis led NPS to conclude that the more stringent criteria would have adversely affected the economic well being of an unacceptably high number of fishermen as well as local communities. The reasons for not selecting alternative criteria are

discussed extensively both above and in the re-proposed rule (64 FR 41854, 41860–63, August 2, 1999).

NPS has placed a copy of the final regulatory flexibility analysis on file in the Administrative Record at the address specified in the ADDRESSES section. Copies are available upon request.

#### *Regulatory Planning and Review*

This document is a significant rule and has been reviewed by the Office of Management and Budget under Executive Order 12866.

a. This rule will not have an annual economic effect of \$100 million or adversely affect an economic sector, productivity, the environment, or other units of government. Jobs in local Alaska communities will be lost and a Federally funded compensation program will mitigate the economic impacts on individuals and the communities. An economic analysis has been completed and is attached (See Regulatory Flexibility Act Section). With this rule we are establishing eligibility requirements and application procedures for obtaining a permit for lifetime access to three commercial fisheries authorized in Glacier Bay proper.

b. This rule will not create inconsistencies with other agencies' actions. Section 123 calls for the Secretary and the State of Alaska to cooperate in the development of a management plan to regulate these ongoing commercial fisheries. Certain inlets or areas of inlets of Glacier Bay proper are either closed to all commercial fishing, or limited to trolling by qualifying fishermen for king salmon during the winter season. Section 123 confirms the statutory prohibition on commercial fishing within the Park's designated wilderness areas, and authorizes compensation for qualifying Dungeness crab fishermen who had fished in designated wilderness waters of the Beardslee Islands and Dundas Bay.

c. This rule will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. This rule implements and establishes eligibility requirements and application procedures for obtaining a permit for lifetime access to three commercial fisheries authorized in Glacier Bay proper.

d. This rule raised novel legal or policy issues regarding the management of fisheries in Glacier Bay National Park.

**Small Business Regulatory Enforcement Fairness Act**

This rule is not a major rule under the Congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2)). This rule:

- a. does not have an effect on the economy of \$100 million or more, as demonstrated in the economic analysis;
- b. will not cause an increase in costs or prices for consumers, individual industries, Federal, State or local government entities, or geographic regions;
- c. does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises (See Regulatory Flexibility Act Section).

**Unfunded Mandates Reform Act**

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*):

- a. This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. This rule does not change the relationship between the NPS and small governments.
- b. The Department has determined and certifies pursuant to the Unfunded Mandates Reform Act that this rule will not impose a cost of \$100 million or more in any given year on local, State or tribal governments or private entities. (See Regulatory Flexibility Act Section.)

**Takings**

In accordance with Executive Order 12630, the rule does not have significant takings implications. No takings of personal property will occur as a result of this rule. Perceived takings due to job loss will be offset by the compensation program. This rule implements and establishes eligibility requirements and application procedures for obtaining a permit for lifetime access to three commercial fisheries authorized in Glacier Bay proper. (See Regulatory Flexibility Act Section.)

**Federalism**

In accordance with Executive Order 12612, the rule does not have significant Federalism effects. The primary effect of this rule is to implement eligibility requirements and application procedures for obtaining a permit for lifetime access to three commercial fisheries authorized in waters of Glacier Bay National Park.

**Civil Justice Reform**

The Department has determined that this rule meets the applicable standards provided in Section 3(a) and 3(b)(2) of

Executive Order 12988. The rule does not unduly burden the judicial system. NPS drafted this rule in plain language to provide clear standards and to ensure that the rule is easily understood. We consulted with the Department of the Interior's Office of the Solicitor during the drafting process.

**Paperwork Reduction Act**

This rule contains information collection requirements subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995. The collection of information contained in section 13.65(a)(5)(iii) of this rule is for issuing a permit for lifetime access to three authorized commercial fisheries within Glacier Bay proper based upon sufficient historical participation. The information collected will be used to determine who qualifies for the issuance of a permit for lifetime access. It is necessary for someone to apply to obtain a permit.

Specifically, NPS needs the following information from an applicant to issue a permit for lifetime access to the salmon troll fishery, Tanner crab pot and ring net fishery, and halibut longline fishery authorized within Glacier Bay proper: (1) Full name, date of birth, mailing address and phone number. (2) A sworn and notarized personal affidavit attesting to the applicant's history of participation as a limited entry permit or license holder in one or more of the three authorized Glacier Bay fisheries during the qualifying years. (3) A copy of a current State or—in the case of halibut—International Pacific Halibut Commission commercial fishing permit card or license that is valid for the area including Glacier Bay proper. (4) Documentation of commercial landings within the statistical units or areas that include Glacier Bay proper during the qualifying period. (5) Any available corroborating information that can assist in a determination of eligibility for the lifetime access permits for the three authorized fisheries within Glacier Bay proper.

NPS has submitted the necessary documentation to the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and received approval for the collection of this information for all areas covered by this rule under permit number 1024-0125.

The public reporting burden for the collection of this information is estimated to average less than two hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and

completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden of these information collection requests, to Information Collection Officer, National Park Service, 800 North Capitol Street, Washington, DC 20001; and the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for Department of the Interior (1024-0125), Washington, DC 20503.

**National Environmental Policy Act**

In April 1998, NPS released a comprehensive Commercial Fishing Environmental Assessment (EA) that described and addressed the potential environmental impacts of the proposed action (the 1997 proposed rule) and four alternatives for managing commercial fishing activities in the marine waters of the park. On October 21, 1998 Section 123 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (Section 123), was passed by Congress and signed into law. Congress passed Section 123 toward the end of what had already been an extended public involvement and comment period on the 1997 proposed rule and 1998 EA. Congress, in passing Section 123, clarified and limited the Secretary of the Interior's discretionary authority with respect to authorizing commercial fishing in Glacier Bay National Park. Section 123 required the Secretary to describe eligibility criteria for the lifetime access permits for Glacier Bay proper, closed certain named inlets and wilderness waters, and clarified that the outer marine waters of the park should remain open to existing fisheries under a cooperatively developed state/federal management plan. Based on the information in the EA a finding of no significant impact was determined and no environmental impact statement will be prepared.

**Effective Date**

In accordance with 5 U.S.C. (d)(3) this rule is effective October 20, 1999, with the exception of paragraphs (a)(10) (i)-(iii) which take effect on January 1, 2000. We find good cause to implement this regulation to meet the requirement mandated by Congress in Pub. L. 106-31 Sec. 501(e).

**List of Subjects in 36 CFR Part 13**

Alaska, National parks, Reporting and recordkeeping requirements.



For the reasons stated in the preamble, the National Park Service amends 36 CFR part 13 as follows:

#### **PART 13—NATIONAL PARK SYSTEM UNITS IN ALASKA**

1. The authority citation for part 13 is amended to read as follows:

**Authority:** 16 U.S.C. 1, 3, 462(k), 3101 *et seq.*; Sec. 13.65 also issued under 16 U.S.C. 1a–2(h), 20, 1361, 1531, 3197; Pub. L. 105–277, 112 Stat. 2681, October 21, 1998; Pub. L. 106–31, 113 Stat. 57, May 21, 1999.

2. Section 13.65 is amended by adding paragraph (a) and removing and reserving paragraphs (b)(5) and (b)(6) to read as follows:

##### **§ 13.65 Glacier Bay National Park and Preserve.**

(a) *Commercial fishing: authorizations, closures and restrictions.*

(1) *What terms do I need to know?*

(i) *Commercial fishing* means conducting fishing activities under the appropriate commercial fishing permits and licenses as required and defined by the State of Alaska.

(ii) *Glacier Bay* means all marine waters within Glacier Bay National Park, including coves and inlets, north of an imaginary line drawn from Point Gustavus to Point Carolus.

(iii) *Outer waters* means all of the non-wilderness marine waters of the park located outside of Glacier Bay.

(2) *Is commercial fishing authorized in the marine waters of Glacier Bay National Park?* Yes—Commercial fishing is authorized within the outer waters of the park and within the non-wilderness waters of Glacier Bay, subject to the provisions of this chapter.

(i) Commercial fishing shall be administered pursuant to A cooperatively developed State/federal park fisheries management plan, international conservation and management treaties, and existing federal and Non-conflicting State law. The management plan shall provide for the protection of park values and purposes, the prohibition on any new or expanded fisheries, and the opportunity to study marine resources.

(ii) Commercial fishing or conducting an associated buying or processing operation in wilderness waters is prohibited.

(iii) A new or expanded fishery is prohibited. The Superintendent shall compile a list of the existing fisheries and gear types used in the outer waters and follow the procedures in §§ 1.5 and 1.7 of this chapter to inform the public.

(iv) Maps and charts showing which marine areas of Glacier Bay are closed

to commercial fishing are available from the Superintendent.

(3) *What types of commercial fishing are authorized in Glacier Bay?* Three types of commercial fishing are authorized in Glacier Bay non-wilderness waters: longline fishing for halibut; pot and ring fishing for Tanner crab; and trolling for salmon.

(i) All other commercial fishing, or a buying or a processing operation not related to an authorized fishery is prohibited in Glacier Bay.

(ii) On October 1, 2000, each fishery will be limited to fishermen who qualify for a non-transferable commercial fishing lifetime access permit (see paragraph (a)(4) of this section). Commercial fishing without a permit issued by the superintendent, or other than in accordance with the terms and conditions of the permit, is prohibited.

(iii) The Superintendent shall include in a permit the terms and conditions that the superintendent deems necessary to protect park resources. Violating a term or condition of the permit is prohibited.

(4) *Who is eligible for a Glacier Bay commercial fishing lifetime access permit?* A Glacier Bay commercial fishing lifetime access permit will be issued by the superintendent to fishermen who have submitted documentation to the superintendent, on or before October 1, 2000, which demonstrates to the satisfaction of the superintendent that:

(i) They possess valid State limited entry commercial fishing permits for the district or statistical area encompassing Glacier Bay for each fishery for which a lifetime access permit is being sought; and,

(ii) They have participated as limited entry permit holders for the district or statistical area encompassing Glacier Bay for each fishery for which a lifetime access permit is being sought.

(A) For the Glacier Bay commercial halibut fishery, the Applicant must have participated as a permit holder for at least two years during the period 1992–1998.

(B) For the Glacier Bay salmon or Tanner crab commercial fisheries, the applicant must have participated as a permit holder for at least three years during the period 1989–1998.

(5) *What documentation is required to apply for a commercial fishing lifetime access permit?* The required documentation includes:

(i) The applicants full name, date of birth, mailing address and phone number;

(ii) A notarized affidavit, sworn by the applicant, attesting to his or her history of participation as a limited permit

holder in Glacier Bay, during the qualifying period, for each fishery for which a lifetime access permit is being sought;

(iii) A copy of the applicant's current State of Alaska limited entry permit and in the case of halibut an International Pacific Halibut Commission quota share, that is valid for the area that includes Glacier Bay, for each fishery for which a lifetime access permit is sought;

(iv) Proof of the applicant's permit and quota share history for the Glacier Bay fishery during the qualifying period;

(v) Documentation of commercial landings for the Glacier Bay fishery during the qualifying periods, i.e., within the statistical unit or area that includes Glacier Bay: for halibut, regulatory sub-area 184; for Tanner crab, statistical areas 114–70 through 114–77. For salmon, the superintendent will consider landing reports from District 114; however, the superintendent may require additional documentation that supports the applicant's declaration of Glacier Bay salmon landings. For halibut and Tanner crab, the superintendent may consider documented commercial landings from the unit or area immediately adjacent to Glacier Bay (in Icy Strait) if additional documentation supports the applicant's declaration that landings occurred in Glacier Bay.

(vi) Any additional corroborating documentation that might assist the superintendent in a timely determination of eligibility for the access permits.

(6) *Where should the documentation for a lifetime access permit be sent?* Before October 1, 2000, all required information (as listed in paragraph (a)(5) of this section) should be sent to: Superintendent, Attn: Access Permit Program, Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, Alaska 99826.

(7) *Who determines eligibility?* The superintendent will make a written determination of an applicant's eligibility for the lifetime access permit based on information provided. A copy of the determination will be mailed to the applicant. If additional information is required to make an eligibility determination, the applicant will be notified in writing of that need and be given an opportunity to provide it.

(8) *Is there an appeals process if a commercial fishing lifetime access permit application is denied?* Yes—If an applicant's request for an a commercial fishing lifetime access permit is denied, the superintendent will provide the applicant with the reasons for the denial in writing within 15 days of the



decision. The applicant may appeal to the Regional Director, Alaska Region, within 180 days. The appeal must substantiate the basis of the applicant's disagreement with the Superintendent's determination. The Regional Director (or his representative) will meet with the applicant to discuss the appeal within 30 days of receiving the appeal. Within 15 days of receipt of written materials and the meeting, if requested, the Regional Director will affirm, reverse, or modify the Superintendent's determination and explain the reasons for the decision in writing. A copy of the decision will be forwarded promptly to the applicant and will be the final agency action.

(9) *How often will commercial fishing lifetime access permit be renewed?* The superintendent will renew lifetime access permit at 5-year intervals for the lifetime of a permittee who continues to hold a valid State limited entry commercial fishing permit, and for halibut an International Pacific Halibut Commission quota share, and is otherwise eligible to participate in the fishery under federal and State law.

(10) *What other closures and restrictions apply to commercial fishermen and commercial fishing vessels?*

The following are prohibited:

(i) Commercial fishing in the waters of Geikie, Tarr, Johns Hopkins and Reid Inlets.

(ii) Commercial fishing in the waters of the west arm of Glacier Bay north of 58°50'N latitude, except commercial fishermen who have been authorized by the superintendent to troll for salmon may troll for king salmon during the period October 1 through April 30, in compliance with state commercial fishing regulations.

(iii) Commercial fishing in the east arm of Glacier Bay, north of an imaginary line running from Point Caroline through the southern point of Garforth Island and extending to the east side of Muir Inlet, except commercial fishermen who have been authorized by the superintendent to troll for salmon may troll for king salmon south of 58°50'N latitude during the period October 1 through April 30, in compliance with state commercial fishing regulations.

(b) \* \* \*

(5) [Reserved]

(6) [Reserved]

\* \* \* \* \*

**Donald J. Barry,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 99-27297 Filed 10-19-99; 8:45 am]

BILLING CODE 4310-70-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300935; FRL-6386-5]

RIN 2070-AB78

### Pyrithiobac Sodium Salt; Time-Limited Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends the time-limited tolerance for residues of the herbicide pyriothiac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 parts per million (ppm). E.I. du Pont de Nemours and Co., Inc., requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1966. The tolerance will expire on September 30, 2001.

**DATES:** This regulation is effective October 20, 1999. Objections and requests for hearings, identified by docket control number OPP-300935, must be received by EPA on or before December 20, 1999.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300935 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-5697, e-mail: tompkins.james@epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

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

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

#### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300935. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of July 14, 1999 (64 FR 37972) (FRL-6085-5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 4F4391) for a tolerance by E.I. du Pont de Nemours & Co., Inc., Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038. This notice included a summary of the petition prepared by du Pont, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.487 be amended by extending the time-limited tolerance for residues of the herbicide pyriithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 ppm. This tolerance will expire on September 30, 2001.

In the **Federal Register** of October 25, 1995 (60 FR 54607) (FRL-4982-8), EPA established a time-limited tolerance for residues of the herbicide pyriithiobac sodium in or on cottonseed at 0.02 ppm. The time limited tolerance expired on September 30, 1997. In the **Federal Register** of October 22, 1997 (62 FR 54778) (FRL-5742-5), EPA established a time-limited tolerance for residues of the herbicide pyriithiobac sodium in or on cottonseed at 0.02 ppm. This time-limited tolerance expires on September 30, 1999.

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

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of pyriithiobac sodium on cottonseed at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyriithiobac sodium are discussed in this unit.

1. A rat acute oral study with a LD<sub>50</sub> of 3,300 milligrams/kilogram (mg/kg) for males and a LD<sub>50</sub> 3,200 mg/kg for females.

2. A 90-day rat feeding study with a no observed adverse effect level (NOAEL) of 50 ppm (3.25 mg/kg/day for males and 4.14 mg/kg/day for females) and a lowest observed adverse effect level (LOAEL) of 500 ppm (31.8 mg/kg/day for males and 40.5 mg/kg/day for females), based on decrease body weight gains and increased rate of hepatic B-oxidation in males.

3. A 90-day mouse feeding study with a NOAEL of 500 ppm (83.1 mg/kg/day for males and 112 mg/kg/day for females) and a LOAEL of 1,500 ppm (263 mg/kg/day for males and 384 mg/kg/day for females) based on increased liver weight and an increased incidence of hepatocellular hypertrophy in males and decreased neutrophil count in females.

4. A 3-month dog feeding study with a NOAEL of 5,000 ppm (165 mg/kg/day) and a LOAEL of 20,000 ppm (626 mg/kg/day), based on decrease red blood cell count, hemoglobin, and hematocrit in females and increased liver weight in both sexes.

5. A 21-day rat dermal study with a dermal irritation NOAEL of 50 mg/kg/day and a dermal irritation LOAEL of 500 mg/kg/day based on increased incidence of erythema and edema, and with a systemic dermal NOAEL of 500 mg/kg/day and a systemic dermal LOAEL of 1,200 mg/kg/day based on body weight gain inhibition.

6. A 90-day rat neurotoxicity screening battery with a systemic NOAEL of 7,000 ppm (466 mg/kg/day for males and 588 mg/kg/day for females) and a Systemic LOAEL of 20,000 ppm (1,376 mg/kg/day for males and 1,609 mg/kg/day for females), based on decreased hind grip strength and increased foot spay in males, and a neurotoxicity NOAEL of 20,000 ppm highest dose tested (HDT).

7. A 78-week dietary carcinogenicity study in mice with a NOAEL of 1,500 ppm 217 mg/kg/day (males) and 319 mg/kg/day (females) and a LOAEL of 5,000 ppm 745 mg/kg/day (males) and 1,101 mg/kg/day (females) based on decreased body weight/gain in both sexes, treatment related increase in the incidence of foci/focus of hepatocellular alternation in males, and increased incidence of glomerulonephropathy murine in both sexes, and an increased incidence of infarct in the kidney and keratopathy of the eyes. There was evidence of carcinogenicity based on significant differences in the pair-wise comparisons of hepatocellular adenomas and combined adenoma/carcinoma in the 150 and 1,500 dose groups (but not at the high dose of 5,000 ppm) with the controls. The carcinogenic effects observed are discussed below.

8. A 24-month rat chronic feeding/carcinogenicity study with a systemic NOAEL of 1,500 ppm (58.7 mg/kg/day for males and 278 mg/kg/day for females) and a systemic LOAEL of 5,000 ppm (200 mg/kg/day for males and 918 mg/kg/day for females) based on decreases in body weight, body weight gains and food efficiency in females, increased incidence of eye lesions in males and females, mild changes in hematology and urinalysis in both sexes, clinical signs suggestive of urinary tract dysfunction in males and females, increased incidence of focal cystic degeneration in the liver in males, increased rate of hepatic peroxisomal B-oxidation in males and an increased incidence of inflammatory and degenerative lesions in the kidney in females. There was evidence of carcinogenicity based on a significant dose-related increasing trend in kidney tubular combined adenoma/carcinoma in male rats and a significant dose related increasing trend in kidney

tubular bilateral and/or unilateral adenomas in females. The carcinogenic effects observed are discussed further below.

9. A 1-year dog chronic feeding study with a NOAEL of 5,000 ppm (143 mg/kg/day for males and 166 mg/kg/day for females) and a LOAEL of 20,000 ppm (580 mg/kg/day for males and 647 mg/kg/day for females) based on decreases in body weight gain and increased liver weight.

10. A 2-generation reproduction study in rats with a maternal NOAEL of 1,500 ppm (103 mg/kg/day) and a maternal LOAEL of 7,500 ppm (508 mg/kg/day), based on decreased body weight/gain and food efficacy. The reproductive and offspring NOAEL is 7,500 ppm (508 mg/kg/day) and the reproductive and offspring LOAEL is 20,000 ppm (1,551 mg/kg/day), based on decreased pup body weight.

11. A developmental toxicity study in rabbits with a maternal and developmental NOAEL of 300 mg/kg and a maternal LOAEL of 1,000 mg/kg based on deaths, decreased body weight gain and feed consumption, increased incidence of clinical signs, and an increase in abortions and a developmental LOAEL of 1,000 mg/kg, based on decreased fetal body weight gain.

12. A developmental toxicity study in rats with a maternal NOAEL 200 mg/kg and a maternal LOAEL of 600 mg/kg due to increased incidence of peritoneal staining. The Developmental NOAEL is 600 mg/kg and the developmental LOAEL is 1,800 mg/kg based on the increased incidence of skeletal variations.

13. No evidence of gene mutation was observed in a test for induction of forward mutations at the HGPRT locus in Chinese hamster ovary cells. No evidence was observed for inducing reverse gene mutation in two independent assays with *Salmonella typhimurium* with and without mammalian metabolic activation. Pyrethrin sodium was negative for the induction of micronuclei in the bone marrow cells of mice, and negative for induction of unscheduled DNA synthesis in rat primary hepatocytes. Pyrethrin sodium was positive for inducing chromosome aberrations assay in human lymphocytes.

14. A rat metabolism study showed that radio labeled pyrethrin sodium is excreted in urine and feces with >90% being eliminated within 48 hours. A sex difference was observed in the excretion and biotransformation. Females excreted a greater amount of the radiolabel in the urine than males following all dosing regimens, with a

corresponding lower amount being eliminated in the feces compared to the males.

#### **B. Toxicological Endpoints**

1. *Acute toxicity.* EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from one-day or single-event exposure.

2. *Short- and intermediate-term toxicity.* EPA has concluded that available evidence does not indicate any evidence of significant toxicity from short- and intermediate-term exposure.

3. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for pyrethrin sodium at 0.587 milligrams/kilogram/day (mg/kg/day). This RfD is based on the systemic NOAEL of 58.7 mg/kg/day for males in the rat chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity.* The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of pyrethrin sodium in mice and rats and has classified pyrethrin sodium as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** in 1986 (51 FR 33992; September 24, 1986) and recommended

that for the purpose of risk characterization a low dose extrapolation model should be applied to the experimental animal tumor data for quantification for human risk (Q1\*). This decision was based on liver adenomas, carcinomas and combined adenoma/carcinomas in the male mouse and rare kidney tubular adenomas, carcinomas and combined adenoma/carcinomas in male rats. The unit risk, Q1\* (mg/kg/day)<sup>-1</sup>, of pyrethrin sodium is 1.05 x 10<sup>-3</sup> (mg/kg/day)<sup>-1</sup> in human equivalents based on male kidney tumors.

#### **C. Exposures and Risks**

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.487) for the residues of pyrethrin sodium in or on the raw agricultural commodity cottonseed at 0.02 ppm until September 30, 1999. Processing studies for cotton have shown that pyrethrin sodium does not concentrate in cottonseed processed commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from herbicide pyrethrin sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) as follows:

Based on assumption that 100% of the crop is treated with pyrethrin sodium, the upper bound limit of the carcinogenic risk from food is calculated in the range of 1 incidence in a billion (1.0 x 10<sup>-9</sup>).

Using the NOAEL of 58.7 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the RfD for systemic effects is 0.58 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.000001 mg/kg/day and utilizes less than 1% of the RfD for the overall U. S. population. For exposure of the most highly exposed subgroup in the population, children aged 1-6 years, the TMRC is 0.000001 mg/kg/day which is still less than 1% of the RfD.

2. *From drinking water.* Pyrethrin sodium concentration in surface water has been estimated by using the Generic Expected Environmental Concentrations (GENEEC) model. The worst case exposure estimate for surface water is 7.76 parts per billion (ppb) and for ground water is 0.778 ppb. Based on the estimated exposures to pyrethrin sodium from drinking water, the percentage of the RfD utilized for children (1-6) would be 0.1% of the RfD. The exposure for the general U.S. population would be less than 0.1% of the RfD.

The worst case estimate for cancer risk from the estimated residues of pyrethrin sodium in drinking water is 2.3 x 10<sup>-7</sup>.

3. *From non-dietary exposure.* There are no non-food uses of pyrethrin sodium currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

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

EPA does not have, at this time, available data to determine whether pyrethrin sodium salt has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyrethrin sodium salt does not appear to produce a toxic metabolite produced by other

substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyrethiobac sodium salt has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

#### *D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute, short- and intermediate-term risk.* EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the use of pyrethiobac sodium on cotton.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyrethiobac sodium from food and water will utilize less than 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years), the aggregate exposure to pyrethiobac sodium from food and drinking water will utilize less than 0.2% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Aggregate cancer risk for U.S. population.* Based on the upper bound potency factor (Q1\*) of  $1.05 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup>, the aggregate upper bound lifetime cancer risk from the use of pyrethiobac sodium on cotton from worst case estimates of residues in food and drinking water is  $2.3 \times 10^{-7}$ .

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of pyrethiobac sodium, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide

information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base for pyrethiobac sodium is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats.

iii. *Conclusion.* There is a complete toxicity data base for pyrethiobac sodium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyrethiobac sodium for children and infants from food and drinking water will utilize less than 0.2% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues.

## **IV. Other Considerations**

### *A. Metabolism in Plants and Animals*

The metabolism of pyrethiobac sodium in plants and animals is adequately understood for purposes of this tolerance.

### *B. Analytical Enforcement Methodology*

Adequate enforcement methodology (High Pressure Liquid Chromatography-Ultra Violet (HPLC-UV) with column switching) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

### *C. Magnitude of Residues*

The nature of the residue in plants is adequately understood for the purposes of this time-limited tolerance.

### *D. International Residue Limits*

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for pyrethiobac sodium.

### *E. Rotational Crop Restrictions*

No tolerances for inadvertent residues of pyrethiobac sodium are required in rotational crops.

## **V. Conclusion**

Therefore, the time-limited tolerance for residues of pyrethiobac sodium in cottonseed at 0.02 ppm is extended until September 30, 2001.

## **VI. Objections and Hearing Requests**

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300935 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before December 20, 1999.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-

5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300935, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

## **VII. Regulatory Assessment Requirements**

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and

Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

#### List of Subjects in 40 CFR Part 180

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

Dated: October 5, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

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

2. In § 180.487, by revising paragraph (a) to read as follows:

#### § 180.487 Pyriithiobac sodium; tolerances for residues.

(a) *General.* Time-limited tolerances to expire on September 30, 2001 are established for residues of the herbicide, pyriithiobac-sodium, sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cottonseed .....	0.02	9/30/01

\* \* \* \* \*

[FR Doc. 99-27392 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 261, 262, and 268

[FRL-6458-8]

RIN 2050-AE05

#### Land Disposal Restrictions Phase IV: Final Rule Promulgating Treatment Standards for Metal Wastes and Mineral Processing Wastes; Mineral Processing Secondary Materials and Bevill Exclusion Issues; Treatment Standards for Hazardous Soils, and Exclusion of Recycled Wood Preserving Wastewaters

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; technical correction.

**SUMMARY:** On May 11, 1999, the Agency published technical amendments correcting the Land Disposal Restrictions (LDR) Phase IV final rule. In today's rule, we are correcting two minor typographical errors and one omission in the May 11th rule. Also, we are correcting three other errors in the LDR Phase IV final rule that came to our attention after the May 11th technical amendments were promulgated.

**EFFECTIVE DATE:** This rule is effective on October 20, 1999.

**ADDRESSES:** The public may obtain a copy of this technical correction at the RCRA information Center (RIC), located at Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia.

**FOR FURTHER INFORMATION CONTACT:** For general information contact the RCRA Hotline at (800) 424-9346 (toll free) or (703) 920-9810 in the Washington, DC metropolitan area. For information on this rule contact Peggy Vyas (5302W), Office of Solid Waste, 401 M Street, SW, Washington, DC 20460, (703) 308-5477, e-mail address is "vyas.peggy@epamail.epa.gov".

#### SUPPLEMENTARY INFORMATION:

#### I. Reasons and Basis for Today's Action

The Agency recently published five rules all related to various aspects of the final Phase IV Land Disposal Restrictions (LDR) rule. These are: the May 12, 1997 LDR final rule (the so-called "Mini" Phase IV Rule, 62 FR 25998), the May 26, 1998 LDR Phase IV final rule (63 FR 28556), the August 31, 1998 administrative stay regarding certain zinc micronutrient fertilizers (63 FR 46332), the September 4, 1998 emergency revisions to the treatment standards for carbamate production wastes (63 FR 172), and the September

24, 1998 revisions to the treatment standards for spent aluminum potliners (63 FR 51254).

On May 11, 1999, the Agency published technical amendments correcting and clarifying certain aspects of all of these rules (64 FR 25408). The May 11th rule contained two minor typographical errors and one omission that we are correcting along with three other errors in the original May 26, 1998 LDR Phase IV final rule that have recently come to our attention.

#### II. Corrections to the May 11, 1999 Technical Amendments

##### A. Arsenic Treatment Standard in K088

In the September 24, 1998 (63 FR 51254) revision of the treatment standards for spent potliners from primary aluminum reduction (K088), the Agency inadvertently omitted the treatment standard adopted for fluoride wastewaters from the entry for K088 in the table of treatment standards in § 268.40. The May 11, 1999 technical amendments restored the fluoride wastewater treatment standard. However, in doing so, EPA inadvertently printed an incorrect measurement unit for the K088 treatment standard for arsenic (a standard which in fact required no correction at all).

The treatment standard for the nonwastewater form of arsenic in K088 (as revised on September 24, 1998) is 26.1 mg/kg, which is to be measured by the total amount of arsenic in the treatment residue. In the May 11, 1999 rule, the treatment standard was incorrectly given as 26.1 mg/l TCLP (a more conventional leaching test not using acid digestion). Today's rule removes the erroneous reference to "mg/l TCLP" for the nonwastewater arsenic standard for the K088 entry in the § 268.40 table.

##### B. Carbamate Treatment Standards

In the September 4, 1998 (63 FR 172) revision of the treatment standards for listed hazardous wastes from carbamate production, the Agency added a paragraph (i) to § 268.40, which inadvertently replaced the existing paragraph (i). The May 11, 1999 technical correction failed to properly reinstate the old paragraph. Today's rule reinserts paragraph § 268.40(i) from the September 4, 1998 rule and redesignates it as § 268.40(j).

##### C. Citation Within § 262.34(a)(4)

Part 262.34 contains the requirements for accumulating hazardous waste prior to treatment. In the May 11, 1999 technical correction, the Agency

amended § 262.34(d)(4) to change an internal citation reference from § 268.7(a)(4) to § 268.7(a)(5) to reflect some other regulatory changes to LDR paperwork requirements that had been adopted on May 12, 1997 (62 FR 25998). However, a parallel correction was not made to § 262.34(a)(4), which also contains the same outdated reference to § 268.7(a)(4). Today we are amending § 262.34(a)(4) to refer to § 268.7(a)(5).

### III. Corrections to the May 26, 1998 LDR Phase IV Final Rule

#### A. Vacated K-Code Wastes

In the LDR Phase IV final rule, the Agency removed K064, K065, K066, K090, and K091 from the table of treatment standards in § 268.40. These five K-code wastes were vacated on April 9, 1999 in *Great Lakes Chemical Co. v EPA* (No. 98–1312 (D.C. Cir.)). However, these wastes still appear in the table of K-code hazardous wastes found in § 261.32. Today's rule removes these vacated K-code wastes from the list in § 261.32.

#### B. § 268.7(a)(3)(ii)

Also in the LDR Phase IV final rule, the Agency revised paragraph § 268.7(a)(3)(ii) by adding a one-time notification for shipping hazardous soil. However, in doing so, the Agency inadvertently replaced other language in that paragraph. Today's rule reinstates the original language and redesignates it as paragraph § 268.7(a)(3)(iii).

#### C. Measuring Compliance With Soil Standards

Lastly, the LDR Phase IV final rule promulgated treatment standards for contaminated soil. The preamble states that compliance with the 90% reduction treatment standard should be measured using the toxicity characteristic leachate procedure (TCLP) for metals and three non-metals: carbon disulfide, cyclohexanone, and methanol (see 63 FR at 28602). Although the preamble to the final rule made it clear that the TCLP test should be used for carbon disulfide, cyclohexanone, and methanol, the regulatory language found in § 268.49(c)(1)(A) did not. We are addressing this discrepancy in today's rule by amending the regulatory language to match the preamble because the preamble accurately represents the Agency's position.

### IV. Analysis Under Executive Order 12866, Executive Order 12875, Executive Order 12898, Executive Order 13045, Executive Order 13084, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act, and the Paperwork Reduction Act

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655, May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the May 12, 1997, the May 26, 1998, the September 4, 1998, and the September 24, 1998 **Federal Register** documents.

### V. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or

contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of October 20, 1999. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

### VI. Immediate Effective Date

EPA is making this rule effective immediately. The rule adopts amendments which are purely technical in that they correct inadvertent printing errors, or mistakes which are clearly inconsistent with the Agency's stated intent. Comment on such changes is unnecessary within the meaning of 5 U.S.C. 553(b)(3)(B). For the same reasons, there is good cause to make the rule effective immediately pursuant to 5 U.S.C. 553(d)(3).

### List of Subjects

#### 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

#### 40 CFR Part 262

Hazardous waste, Labeling, Manifest, Reporting and recordkeeping requirements.

#### 40 CFR Part 268

Hazardous waste, Reporting and recordkeeping requirements.

Dated: September 21, 1999.

**Michael Shapiro,**

*Acting Assistant Administrator, Office of Solid Waste and Emergency Response.*

For the reasons set forth in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

### PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

#### Subpart A—General

1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

#### § 261.32 [Amended]

2. The table in § 261.32 is amended by removing the entries for K064, K065, K066, K090, and K091.



**PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE**

3. The authority citation for part 262 continues to read as follows:

**Authority:** 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

**Subpart C—Pre-Transport Requirements**

4. Section 262.34 is amended by revising paragraph (a)(4) to read as follows:

**§ 262.34 Accumulation time.**

\* \* \* \* \*

(a) \* \* \*

(4) The generator complies with the requirements for owners or operators in subparts C and D in 40 CFR part 265, with § 265.16, and with 40 CFR 268.7(a)(5).

\* \* \* \* \*

**PART 268—LAND DISPOSAL RESTRICTIONS**

5. The authority citation for part 268 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, and 6924.

**Subpart A—General**

6. Section 268.7 is amended by adding paragraph (a)(3)(iii) to read as follows:

**§ 268.7 Testing, tracking, and recordkeeping requirements for generators, treaters, and disposal facilities.**

(a) \* \* \*

(3) \* \* \*

(iii) If the waste changes, the generator must send a new notice and certification to the receiving facility, and place a copy in their files. Generators of hazardous debris excluded from the definition of hazardous waste under § 261.3(f) of this chapter are not subject to these requirements.

\* \* \* \* \*

7. Section 268.40 is amended by revising paragraph (j), and the table at the end of the section is amended by revising the entry for K088 to read as follows:

**§ 268.40 Applicability of treatment standards.**

\* \* \* \* \*

(j) Effective September 4, 1998, the treatment standards for the wastes specified in 40 CFR 261.33 as EPA Hazardous Waste numbers P185, P191, P192, P197, U364, U394, and U395 may be satisfied by either meeting the constituent concentrations presented in the table "Treatment Standards for Hazardous Wastes" in this section, or by treating the waste by the following technologies: combustion, as defined by the technology code CMBST at § 268.42 Table 1 of this Part, for nonwastewaters; and, biodegradation as defined by the technology code BIODG, carbon adsorption as defined by the technology code CARBN, chemical oxidation as defined by the technology code CHOXD, or combustion as defined as technology code CMBST at § 268.42 Table 1 of this Part, for wastewaters.

**TREATMENT STANDARDS FOR HAZARDOUS WASTES**

[Note: NA means not applicable]

Waste code	Waste description and treatment/regulatory subcategory <sup>1</sup>	Regulation hazardous constituent		Wastewaters—Concentration in mg/l <sup>3</sup> ; of technology code <sup>4</sup>	Nonwastewaters—Concentration in mg/kg <sup>5</sup> unless noted as "mg/l TCLP"; or technology code
		Common name	CAS <sup>2</sup> No.		
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
K088 .....	Spent potliners from primary aluminum reduction..	Acenaphthene .....	83–32–9	0.059	3.4
		Anthracene .....	120–12–7	0.059	3.4
		Benz(a)anthracene .....	56–55–3	0.059	3.4
		Benzo(a)pyrene .....	50–32–8	0.061	3.4
		Benzo(b)fluoranthene .....	205–99–2	0.11	6.8
		Benzo(k)fluoranthene .....	207–08–9	0.11	6.8
		Benzo(g,h,i)perylene .....	191–24–2	0.0055	1.8
		Chrysene .....	218–01–9	0.059	3.4
		Dibenz(a,h)anthracene .....	53–70–3	0.055	8.2
		Fluoranthene .....	206–44–0	0.068	3.4
		Indeno(1,2,3-c,d)pyrene .....	193–39–5	0.0055	3.4
		Penanthrene .....	85–01–8	0.059	5.6
		Pyrene .....	129–00–0	0.067	8.2
		Antimony .....	7440–36–0	1.9	1.15 mg/l TCLP.
		Arsenic .....	7440–38–2	1.4	26.1
		Barium .....	7440–39–3	1.2	21 mg/l TCLP.
		Beryllium .....	7440–41–7	0.82	1.22 mg/l TCLP.
		Cadmium .....	7440–43–9	0.69	0.11 mg/l TCLP.
		Chromium (Total) .....	7440–47–3	2.77	0.60 mg/l TCLP.
		Lead .....	7439–92–1	0.69	0.75 mg/l TCLP.
		Mercury .....	7439–97–6	0.15	0.025 mg/l TCLP.
		Nickel .....	7440–02–0	3.98	11 mg/l TCLP.
		Selenium .....	7782–49–2	0.82	5.7 mg/l TCLP.
		Silver .....	7440–22–4	0.43	0.14 mg/l TCLP.
		Cyanide (Total) <sup>7</sup> .....	57–12–5	1.2	590
		Cyanide (Amenable) <sup>7</sup> .....	57–12–5	0.86	30
		Fluoride .....	16984–48–8	35	NA.



Footnotes to Treatment Standard Table 268.40

<sup>1</sup> The waste descriptions provided in this table do not replace waste descriptions in 40 CFR 261. Descriptions of Treatment/Regulatory Subcategories are provided, as needed, to distinguish between applicability of different standards.

<sup>2</sup> CAS means Chemical Abstract Services. When the waste code and/or regulated constituents are described as a combination of a chemical with its salts and/or esters, the CAS number is given for the parent compound only.

<sup>3</sup> Concentration standards for wastewaters are expressed in mg/l and are based on analysis of composite samples.

<sup>4</sup> All treatment standards expressed as a Technology Code or combination of Technology Codes are explained in detail in 40 CFR 268.42 Table 1—Technology Codes and Descriptions of Technology-Based Standards.

<sup>5</sup> Except for Metals (EP or TCLP) and Cyanides (Total and Amenable) the nonwastewater treatment standards expressed as a concentration were established, in part, based upon incineration in units operated in accordance with the technical requirements of 40 CFR Part 264 Subpart O or Part 265 Subpart O, or based upon combustion in fuel substitution units operating in accordance with applicable technical requirements. A facility may comply with these treatment standards according to provisions in 40 CFR 268.40(d). All concentration standards for nonwastewaters are based on analysis of grab samples.

<sup>7</sup> Both Cyanides (Total) and Cyanides (Amenable) for nonwastewaters are to be analyzed using Method 9010 or 9012, found in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in 40 CFR 260.11, with a sample size of 10 grams and a distillation time of one hour and 15 minutes.

8. Section 268.49 is amended by revising paragraphs (c)(1) (A) and (B) to read as follows:

**§ 268.49 Alternative LDR treatment standards for contaminated soil.**

\* \* \* \* \*

(c) \* \* \*  
(1) \* \* \*

(A) For non-metals except carbon disulfide, cyclohexanone, and methanol, treatment must achieve 90 percent reduction in total constituent concentrations, except as provided by paragraph (c)(1)(C) of this section.

(B) For metals and carbon disulfide, cyclohexanone, and methanol, treatment must achieve 90 percent reduction in constituent concentrations as measured in leachate from the treated media (tested according to the TCLP) or 90 percent reduction in total constituent concentrations (when a metal removal treatment technology is used), except as provided by paragraph (c)(1)(C) of this section.

\* \* \* \* \*

[FR Doc. 99-27138 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 635**

[I.D. 100899B]

**Atlantic Highly Migratory Species Fisheries; Atlantic Bluefin Tuna**

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

**ACTION:** Opening of General category New York Bight fishery.

**SUMMARY:** NMFS opens the Atlantic Bluefin Tuna (BFT) General category New York Bight fishery. This action is being taken to provide for General category fishing opportunities in the

New York Bight area only and to ensure additional collection of biological assessment and monitoring data.

**DATES:** Effective 1 a.m. on October 16, 1999, until the date that the set-aside quota is determined to have been taken, which will be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:**

Sarah McLaughlin or Pat Scida, 978-281-9260.

**SUPPLEMENTARY INFORMATION:**

Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT landings quota recommended by the International Commission for the Conservation of Atlantic Tunas among the various domestic fishing categories. The General category landings quota, including time-period subquotas and the New York Bight set-aside, are specified annually as required under § 635.27(a)(1). The 1999 General category quota and effort control specifications were issued June 1, 1999 (64 FR 29806, June 3, 1999).

**Opening of the New York Bight fishery**

The New York Bight set-aside area is defined as the waters south and west of a straight line originating at a point on the southern shore of Long Island at 72°27' W. long. (Shinnecock Inlet) and running SSE 150° true, and north of 38°47' N. lat. (Delaware Bay). Under § 635.27(a)(1)(iii), NMFS may make available all or part of the 10 mt landings quota set aside for the New York Bight area when the coastwide General category fishery has been closed in any quota period. Previously, NMFS closed the coastwide General category fishery on October 3, 1999. At that time, NMFS announced that it would open the New York Bight fishery when it is determined that large medium and giant

BFT are available in the New York Bight area. Allowing a few days transition between the closure of the coastwide fishery and the opening of the New York Bight fishery reduces concerns regarding enforcement of regulations applicable to that area. The New York Bight fishery will open effective 1 a.m., Saturday, October 16, 1999, until the date that the set-aside quota of 10 mt is determined to have been taken, which will be published in the **Federal Register**.

For vessels permitted in the General category: Upon the effective date of the New York Bight opening, retaining or landing large medium or giant BFT is authorized only within the set-aside area, until the set-aside quota for that area has been harvested. BFT harvested from waters outside the defined set-aside area may not be brought into the set-aside area. General category permit holders may tag and release BFT in all areas while the General category is closed, subject to the requirements of the tag-and-release program at § 635.26.

For vessels permitted in the Charter/Headboat category: When participating in the General category New York Bight fishery, i.e., fishing for large medium and giant BFT intended for sale, Charter/Headboat category vessels are subject to the same rules as General category vessels. Charter/Headboat category vessels may continue to fish in all areas under the Angling category regulations while the Angling category is open. Vessels permitted in the Charter/Headboat category that are still eligible for the Angling category trophy fish allowance under § 635.23(c)(1) or (2) may land one large medium or giant BFT prior to May 31, 2000. Trophy BFT may not be sold.

The announcement of the New York Bight fishery closure date will be filed with the Office of the Federal Register, and further communicated through the Highly Migratory Species (HMS) Fax Network, the Atlantic Tunas Information Line, NOAA weather radio,

and Coast Guard Notice to Mariners. Although notification of the closure will be provided as far in advance as possible, fishermen are encouraged to call the Atlantic Tunas Information Line to check the status of the fishery before leaving for a fishing trip. The phone numbers for the Atlantic Tunas Information Line are (978) 281-9305 and (888) USA-TUNA.

#### Classification

This action is taken under § 635.27(a)(1) and is exempt from review under E.O. 12866.

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

Dated: October 14, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27304 Filed 10-14-99; 4:59 pm]

BILLING CODE 3510-22-F

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 679

[Docket No. 990304062-9062-01; I.D. 101599D]

##### Fisheries of the Economic Exclusive Zone Off Alaska; Trawl Gear in the Gulf of Alaska

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

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for groundfish by vessels using trawl gear in the Gulf of Alaska (GOA), except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA open to directed fishing for pollock. This action is necessary because the 1999 Pacific halibut prohibited species catch (PSC) limit for trawl gear in the GOA has been caught.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), October 16, 1999, until 1200 hrs, A.l.t., December 31, 1999.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 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.

The Final 1999 Harvest Specifications of Groundfish for the GOA (64 FR 12094, March 11, 1999) established the 1999 Pacific halibut PSC limit for vessels using trawl gear at 2,000 metric tons (mt). The Administrator, Alaska Region, has determined, in accordance with § 679.21(d)(7)(i), that vessels engaged in directed fishing for groundfish with trawl gear in the GOA have caught the 1999 Pacific halibut PSC limit. Therefore, NMFS is closing the directed fishery for groundfish by vessels using trawl gear in the GOA, except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA that remain open to directed fishing for pollock.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

#### Classification

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately to prevent exceeding the 1999 trawl Pacific halibut PSC limit. Providing prior notice and an opportunity for public comment on this action is impracticable and contrary to the public interest. The fleet will soon take the 1999 trawl Pacific halibut PSC limit in the GOA. Further delay would only result in the 1999 trawl Pacific halibut PSC limit being exceeded. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by 50 CFR 679.21 and is exempt from review under E.O. 12866.

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

Dated: October 15, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27382 Filed 10-15-99; 3:23 pm]

BILLING CODE 3510-22-F

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 679

[Docket No. 990304063-9063-01; I.D. 101599E]

##### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod Fishery by Vessels Using Trawl Gear in Bering Sea and Aleutian Islands Management Area

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

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for Pacific cod by vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod fishery category.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), October 18, 1999, until 2400 hrs, A.l.t., December 31, 1999.

**FOR FURTHER INFORMATION CONTACT:** Andrew Smoker, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at Subpart H of 50 CFR part 600 and 50 CFR part 679.

The Final 1999 Harvest Specifications of Groundfish (64 FR 12103, March 11, 1999) established the halibut bycatch mortality allowance specified for the BSAI trawl Pacific cod fishery, which is defined at § 679.21(e)(3)(iv)(E), as 1,473 metric tons.

In accordance with § 679.21(e)(7)(v), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod fishery in the BSAI has been caught. Consequently, the Regional Administrator is closing directed fishing for Pacific cod by vessels using trawl gear in the BSAI.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately to prevent exceeding the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod fishery category. Providing prior notice and an opportunity for public comment on this action is impracticable and contrary to the public interest. The fleet will soon take the allowance. Further delay would only result in the 1999 halibut bycatch mortality allowance for the trawl Pacific cod fishery category being exceeded. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under U.S.C. 553(d), a delay in the effective date is hereby waived.

#### **Classification**

This action is required by 50 CFR 679.21 and is exempt from review under E.O. 12866.

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

**Dated:** October 15, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27381 Filed 10-15-99; 3:22 pm]

**BILLING CODE 3510-22-F**

#### **DEPARTMENT OF COMMERCE**

##### **National Oceanic and Atmospheric Administration**

##### **50 CFR Part 679**

[Docket No. 990304063-9063-01; I.D. 101599C]

##### **Fisheries of the Exclusive Economic Zone Off Alaska; Yellowfin Sole by Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands**

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

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for yellowfin sole by vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 1999 halibut bycatch mortality allowance specified for the trawl yellowfin sole fishery category.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), October 15, 1999, until 2400 hrs, A.l.t., December 31, 1999.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Final 1999 Harvest Specifications of Groundfish established the halibut bycatch mortality allowance specified for the BSAI trawl yellowfin sole fishery, which is defined at § 679.21(e)(3)(iv)(B)(1), as 955 metric tons (64 FR 12103, March 11, 1999).

In accordance with § 679.21(e)(7)(v), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 1999 halibut bycatch mortality allowance specified for the trawl yellowfin sole fishery in the BSAI has been caught. Consequently, the Regional Administrator is closing directed fishing for yellowfin sole by vessels using trawl gear in the BSAI.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

#### **Classification**

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately to prevent exceeding the 1999 halibut bycatch mortality allowance specified for the trawl yellowfin sole fishery category. A delay in the effective date is impracticable and contrary to the public interest. The fleet will soon take the allowance. Further delay would only result in the 1999 halibut bycatch mortality allowance for the trawl yellowfin sole fishery category being exceeded. NMFS finds for good cause that the implementation of this action can not be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under E.O. 12866.

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

**Dated:** October 15, 1999

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27380 Filed 10-15-99; 3:22 pm]

**BILLING CODE 3510-22-F**

##### **DEPARTMENT OF COMMERCE National Oceanic and Atmospheric Administration**

##### **50 CFR Part 679**

[Docket No. 990304063-9063-01; I.D. 101299E]

##### **Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pollock**

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

**ACTION:** Reallocation.

**SUMMARY:** NMFS is reallocating projected unused amounts of Bering Sea subarea (BS) pollock from the incidental catch account to the directed fisheries. This action is necessary to allow the 1999 total allowable catch (TAC) of pollock to be harvested.

**DATES:** Effective October 15, 1999.

**FOR FURTHER INFORMATION CONTACT:** Andrew Smoker, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In accordance with section 206(b) of the American Fisheries Act (AFA), NMFS specified a pollock incidental catch allowance equal to 6 percent of the pollock total allowable catch after subtraction of the 10 percent Community Development Quota reserve in the Final 1999 Harvest Specifications for Groundfish for the BSAI (64 FR 12103, March 11, 1999).

As of October 2, 1999, the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that approximately 5,000 metric tons (mt) of pollock remain in the incidental catch account. Based on projected harvest rates of other groundfish species and the expected bycatch of pollock in those fisheries, the Regional Administrator has determined that 2,000 mt of pollock specified to the incidental catch account will not be necessary as incidental catch. Therefore, NMFS is apportioning the projected unused amount, 2,000 mt, of pollock

from the incidental catch account to the directed fishing allowances established at section 206(b). This transfer will increase the allocation to catcher vessels harvesting pollock for processing by the inshore component by 1,000 mt, to catcher/processors and catcher vessels harvesting pollock for processing by catcher processors in the offshore component by 800 mt, and to catcher vessels harvesting pollock for processing by motherships in the offshore component by 200 mt. Pursuant to section 210(c) of the AFA, no less than 8.5 percent of the 800 mt allocated to catcher processors in the offshore component, 68 mt, will be available for harvest only by eligible catcher vessels delivering to listed catcher processors.

Regulations in the emergency interim rule establishing Steller sea lion protection measures for the pollock fisheries off Alaska allow for catch to occur within a season so that pollock removals from all sectors do not exceed 30 percent of the annual TAC (64 FR 3437, January 22, 1999). See § 679.20(a)(5)(i)(C). Thirty percent of the annual pollock TAC is equal to 297,600 mt. With this apportionment the C season catch for the three combined directed fisheries and the CDQ fishery will be 265,000 mt thereby not violating the 30 percent restriction.

#### Classification

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately in order to allow full utilization of the pollock TAC. A delay in the effective date is impracticable and contrary to the public interest. Further delay would only disrupt the AFA and FMP's objective of providing pollock for harvest in directed fisheries. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is taken under 50 CFR 679.20, and is exempt from OMB review under E.O. 12866.

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

Dated: October 14, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27379 Filed 10-15-99; 3:24 pm]

BILLING CODE 3510-22-F

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 679

[Docket No. 990304063-9063-01; I.D. 101599F]

##### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Hook-and-line and Pot Gear in the Bering Sea and Aleutian Islands

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

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for Pacific cod by vessels using hook-and-line and pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 1999 total allowable catch (TAC) of Pacific cod allocated for vessels using hook-and-line and pot gear in this area.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), October 19, 1999, until 2400 hrs, A.l.t., December 31, 1999.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Final 1999 Harvest Specifications of Groundfish for the BSAI (64 FR 12103, March 11, 1999), and subsequent

reallocation (64 FR 52472, September 29, 1999) established the 1999 TAC of Pacific cod allocated to vessels using hook-and-line and pot gear in the BSAI as 91,300 metric tons (mt). See § 679.20(c)(3)(iii) and § 679.20(a)(7)(i)(A).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 1999 TAC of Pacific cod allocated to vessels using hook-and-line and pot gear in the BSAI will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 91,200 mt, and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is closing directed fishing for Pacific cod for vessels using hook-and-line and pot gear in the BSAI.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

#### Classification

This action responds to the best available information recently obtained from the fishery. It must be implemented immediately in order to prevent overharvesting the 1999 TAC of Pacific cod allocated to vessels using hook-and-line and pot gear in the BSAI. A delay in the effective date is impracticable and contrary to the public interest. The Pacific cod directed fishing allowance established for vessels using hook-and-line and pot gear will soon be reached. Further delay would only result in overharvest. NMFS finds for good cause that the implementation of this action can not be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under E.O. 12866.

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

Dated: October 15, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27378 Filed 10-15-99; 3:23 pm]

BILLING CODE 3510-22-F

# Proposed Rules

Federal Register

Vol. 64, No. 202

Wednesday, October 20, 1999

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.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

[Docket No. PRM-50-61]

#### Nuclear Energy Institute; Withdrawal of Petition for Rulemaking

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Withdrawal of petition for rulemaking.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) has determined that a petition for rulemaking submitted by the Nuclear Energy Institute (NEI) (PRM-50-61), in which the petitioner requested that the NRC amend its fire protection regulations, has effectively been withdrawn by NEI. In subsequent correspondence with the NRC, the petitioner expressed a change of position that obviated the need for a proposed rulemaking requested by the petition. Specifically, the petitioner requested that the NRC cancel the proposed fire protection rulemaking instead of deferring it. As an alternative to the rulemaking requested in the petition, the NRC, in cooperation with the National Fire Protection Association (NFPA) and stakeholders, is pursuing the development of a risk-informed, performance-based consensus standard for fire protection at nuclear power plants. If the consensus standard is successfully developed, the NRC may adopt it in a future rulemaking as an alternative method of meeting the NRC fire protection requirements. Accordingly, the NRC is not taking any further action on the petition since it has, in effect, been withdrawn by the petitioner.

**ADDRESSES:** Copies of the petition for rulemaking, the public comments received, and the NRC's letter to the petitioner are available for public inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level),

Washington, DC 20012-7082, telephone: (202) 634-3273.

#### FOR FURTHER INFORMATION CONTACT:

Daniele Oudinot, Division of Systems Safety and Analysis, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Telephone: (301) 415-3731, e-mail dho@nrc.gov.

**SUPPLEMENTARY INFORMATION:** On June 6, 1995 (60 FR 29784), the NRC published a notice of receipt of a petition for rulemaking filed by NEI. The petitioner requested that the NRC revise 10 CFR 50.48 and add an Appendix S to 10 CFR part 50. In a letter dated February 2, 1995, to John C. Hoyle, then-Acting Secretary of the NRC, William H. Rasin, then-president of NEI, submitted a Petition for Rulemaking (PRM-50-61). In the petition, NEI requested that the NRC amend 10 CFR 50.48 and add an Appendix S to 10 CFR part 50 providing for an alternative to the current regulation in Appendix R to 10 CFR part 50, "Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979." In its petition, NEI stated that the rulemaking would make the fire protection regulations less prescriptive and more performance oriented and risk based.

In a letter dated December 11, 1997, from Ralph Beedle, Senior Vice President and Chief Nuclear Officer, NEI, to L. Joseph Callan, formerly NRC Executive Director for Operations, Mr. Beedle presented the results of a survey of all chief nuclear officers of operating reactors concerning the fire protection rulemaking. As expressed in that survey, industry's position was that a new fire protection rule was neither desired nor considered necessary to ensure or improve safety. In his letter, Mr. Beedle acknowledged that this represented, on the part of the industry, a change of position from that previously communicated in NEI's petition for rulemaking of February 2, 1995.

On March 26, 1998, the NRC staff submitted SECY-98-058, "Development of a Risk-Informed, Performance-Based Regulation for Fire Protection at Nuclear Power Plants," to the Commission. In SECY-98-058, the staff recommended that the fire protection rulemaking be deferred and that the NRC, in cooperation with the NFPA and the stakeholders, develop a performance-

based and risk-informed consensus standard for fire protection for nuclear power plants. The NRC staff proposed that if the standard were successfully developed, the NRC could adopt it in a future rulemaking as an alternate way of meeting NRC fire protection requirements specified in 10 CFR 50.48 and Appendix R to 10 CFR part 50. The Commission approved the NRC staff's proposal in a staff requirements memorandum on SECY-99-058 dated June 30, 1998.

NEI reiterated its approval and support for the development of the NFPA standard instead of the proposed Appendix S in a letter of May 5, 1998, from Mr. Beedle to the former NRC Chairman Shirley Jackson. In that letter, Mr. Beedle stated: "The industry sees no safety benefit in replacing 10 CFR 50.48 and Appendix R with a new fire protection rule \* \* \*. It is essential that the industry participate extensively in the development and review of any guidance to ensure that licensees and NRC staff have a common understanding \* \* \*. The NRC staff should continue to support, as does industry, the National Fire Protection Association (NFPA) process to develop NFPA 805 \* \* \*. The fire protection rulemaking should be canceled rather than deferred."

The NRC sent a letter to the petitioner on August 20, 1999, stating that, on the basis of NEI's letters of December 11, 1997, and May 5, 1998, the NRC concluded that NEI has, in effect, withdrawn its petition for rulemaking regarding nuclear power plant fire protection. The NRC also stated that, unless NEI disagreed with this conclusion and responded in writing within 14 days of the August 20, 1999, letter, the NRC would publish a notice of withdrawal of the petition in the **Federal Register**. NEI did not respond to NRC's August 20, 1999 letter. Therefore, NRC deems the NEI petition of February 2, 1995 (PRM-50-61) to be withdrawn.

Dated at Rockville, Maryland, this 14th day of October, 1999.

For the Nuclear Regulatory Commission.

**Annette Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. 99-27360 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-300913A; FRL-6385-4]

RIN 2070-AB78

**Cyromazine; Pesticide Tolerance Correction**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: EPA issued a proposed rule in the **Federal Register** of September 15, 1999 proposing tolerances for cyromazine. This document is being issued to correct the entries for onion, dry bulb, and onion, green.

DATES: Comments, identified by docket control number OPP-300913A, must be received on or before November 15, 1999.

FOR FURTHER INFORMATION CONTACT: By mail: Linda DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 202, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5428; e-mail: deluise.linda@epa.gov.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit II. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-300913A in the subject line on the first page of your response.

**SUPPLEMENTARY INFORMATION:****I. Does this Action Apply to Me?**

The Agency included a list of those who may be potentially affected in the proposed rule (64 FR 50043, September 15, 1999. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under "FOR FURTHER INFORMATION CONTACT."

**II. How Can I Get Additional Information or Copies of this or Other Support Documents?**

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**- Environmental

Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300913A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

**III. What Does this Technical Correction Do?**

Proposed tolerances for cyromazine on various commodities were published in the **Federal Register** on September 15, 1999 (64 FR 50043) (FRL-6098-7). This technical correction corrects the proposed tolerance levels for cyromazine on onion, dry bulb, and onion, green which were incorrectly shown in the codified text of 40 CFR 180.414.

**IV. Do Any of the Regulatory Assessment Requirements Apply to this Action?**

This action proposes to establish tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). In addition this proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28,

1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

**List of Subjects in 40 CFR Part 180**

Environmental Protection.

Dated: October 5, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, FR Doc 99-24047 published in the **Federal Register** of September 15, 1999 (64 FR 50043) amending 40 CFR part 180 is corrected as follows:

**PART 180—[AMENDED]**

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

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

2. In § 180.414, the table to paragraph (a), the entries for onion, dry bulb; and onion, green are corrected to read as follows:

**§ 180.414 Cyromazine; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Onion, dry bulb .....	0.1
Onion, green .....	2.0
* * * * *	*

\* \* \* \* \*

[FR Doc. 99-27146 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-F

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary****49 CFR Chapter III**

[FHWA Docket No. FHWA-98-3656]

RIN 2125-AE40

**Public Meetings To Discuss Responsibilities for the Inspection, Repair, and Maintenance of Intermodal Container Chassis and Trailers****AGENCY:** Office of the Secretary, DOT.**ACTION:** Notice of public listening sessions.

**SUMMARY:** The Office of the Secretary is announcing a series of public meetings for motor carriers, businesses that offer intermodal container chassis and trailers for transportation, and interested parties to discuss current inspection, repair, and maintenance practices in the intermodal transportation industry for ensuring that chassis and trailers are in safe and proper operating condition at all times. Representatives from the Federal Highway Administration, Federal Railroad Administration (FRA), Maritime Administration (MARAD), and the Office of the Secretary of Transportation (OST) will participate in the listening sessions which are intended to help the DOT broaden its knowledge of the safety implications of industry practices where terminal operators or other parties tender intermodal equipment (container chassis and trailers) to motor carriers. All oral comments will be transcribed and placed in the public docket identified at the beginning of this notice.

**DATES:**

November 2, 1999, in Seattle, Washington

November 9, 1999, in Des Plaines (Chicago), Illinois

November 15, 1999, in Jamaica (New York City), New York

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for addresses of the public meetings.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard H. Singer, Office of Motor Carrier Research and Standards, HMCS-10, (202) 366-4009, U.S. Department of Transportation; or Mr. Charles E. Medalen, Office of the Chief Counsel, HCC-20, (202) 366-1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. [TDD number for the hearing impaired: 1-800-699-7828] Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

Internet users can access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resource locator (URL): <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. When using the document management system (dms) website, please enter docket number 3656 to search for comments on this rulemaking. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the **Federal Register's** home page at <http://www.nara.gov/fedreg> and the Government Printing Office's database at <http://www.access.gpo.gov/nara>.

**Background**

The American Trucking Associations, Inc. and the ATA Intermodal Conference (the petitioners) filed a petition for rulemaking on March 17, 1997, to amend 49 CFR parts 390 and 396 of the Federal Motor Carrier Safety Regulations (FMCSRs). The petitioners asked the FHWA to require parties that tender intermodal equipment to motor carriers to ensure the "roadworthiness" of that equipment. The petitioners argued that poor maintenance of intermodal equipment is a serious safety problem and contend that motor carriers have limited opportunity to maintain this equipment and other parties that do have the opportunity often fail to do so. The FHWA was requested to revise the FMCSRs to make the owner or operator of such equipment responsible for the roadworthiness of the vehicles it tenders to motor carriers.

On February 17, 1999, the FHWA published an ANPRM (64 FR 7849) seeking information on the extent of the concerns identified by the petitioners, and public comments on the solution proposed by the petitioners, i.e., to mandate joint responsibility between the equipment provider and the motor carrier for maintaining this type of intermodal equipment. The closing date for comments was April 19, 1999.

On April 2, 1999, the FHWA received a request from the petitioners to extend the comment period to allow them to collect and analyze certain data needed to respond to questions in the ANPRM. The petitioners indicated that they had been trying to develop current and accurate information to respond to the 14 specific questions the FHWA asked in the ANPRM.

On May 5, 1999 (64 FR 24128), the FHWA granted the petitioners' request and extended the docket comment period to August 30, 1999, because of the difficulty the petitioners and others were experiencing in gathering and analyzing roadside inspection and maintenance data necessary to provide meaningful responses to questions in the ANPRM. To augment the information received in response to the ANPRM questions, the docket for this rulemaking will accept additional comments, proceedings transcripts, and information generated as a result of the listening sessions.

**Purpose of the Public Meetings**

The Department of Transportation must ensure that it has considered all the pertinent issues that could affect any potential rulemaking changes. The Department has received numerous comments in response to its advance notice of proposed rulemaking but believes additional information could be obtained through public meetings.

The public meetings will be structured as "listening sessions" to emphasize interactive discussion among the participants. Representatives from the Office of the Secretary of Transportation, FHWA, FRA, and MARAD will attend the listening sessions to participate in a dialogue with the public on the issues associated with a potential rulemaking on the roadability of intermodal equipment.

Copies of the February 17 ANPRM that include the Department's 14 questions on intermodal equipment roadability will be made available to participants at each of the listening sessions. Participants also will be given the opportunity to submit questions that they would like to hear discussed by others in attendance at the listening session. It should be noted that these listening sessions are not public hearings, and participants are discouraged from simply reading prepared statements.

Participants who wish to submit written comments or statements should submit the information to the public docket identified at the beginning of this notice. Comments should be mailed to: Docket Clerk, U.S. DOT Dockets, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001. All comments received will be available for examination at the preceding address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard. Comments made during the



meeting will be transcribed to preserve an accurate record of the discussion.

### Meeting Information

*November 2, 1999—Seattle, Washington*

The Seattle listening session will be held at the U.S. Coast Guard Integrated Support Command Seattle located at 1519 Alaskan Way South, Seattle, Washington 98134. The listening session facility is located in the Healy Training Room in Building 7 of the Pier 36 Complex. The listening session is scheduled to run from 9:00am until 12:00 noon; following a break for lunch, the afternoon portion will reconvene at 1:30pm and conclude at 4:30pm.

Since access to the Coast Guard base is controlled for security, all visitors must show government-issued photo identification (e.g., driver's license, local/State/Federal agency identification, etc.) and sign-in with the security officer located at the entrance to the base. There is no parking available on-site, and visitors should look for parking spaces along Alaskan Way and under the Highway 99 viaduct.

*November 9, 1999—Des Plaines, Illinois*

The Chicago listening session will be held at the Federal Aviation Administration (FAA) Great Lakes Region Headquarters at 2300 East Devon Avenue, Des Plaines, Illinois 60018. The listening session facility is located in the Michigan Conference Room of the New Conference Center in the O'Hare Lake Office Center. The listening session is scheduled to run from 9:00 am until 12:00 noon; following a break for lunch, the afternoon portion will reconvene at 1:30pm and conclude at 4:30pm.

Since access to the FAA facility is controlled for security, all visitors must show government-issued photo identification (e.g., driver's license, local/State/Federal agency identification, etc.), sign-in with the security officer located at the entrance to the building, and wear a visitor's badge at all times while in the facility. There is parking available on-site.

*November 15, 1999—Jamaica, New York*

The New York City listening session will be held at the Federal Aviation Administration Eastern Region Headquarters at JFK International Airport in Jamaica, New York 11430. The listening session facility is located in Room 223 of Building 111, directly off the Van Wyck Expressway. The listening session is scheduled to run from 9:00am until 12:00 noon; following a break for lunch, the afternoon portion will reconvene at 1:30pm and conclude at 4:30 pm.

Since access to the FAA facility is controlled for security, all visitors must show government-issued photo identification (e.g., driver's license, local/State/Federal agency identification, etc.), sign-in with the security officer located at the entrance to the building, and wear a visitor's badge at all times while in the facility. As parking at Building 111 is limited, public transportation is recommended. The Green Bus Line "Q10" bus stops directly in front of, and behind, the building. Connections to the "Q10" can be made from the New York City "A", "E", and "F" subway lines.

**Authority:** 49 U.S.C. 504, 31133, 31136, and 31502; and 49 CFR 1.48.

Issued on October 13, 1999 at Washington, DC.

**William M. Wood,**

*Senior Transportation Specialist, Department of Transportation.*

[FR Doc. 99-27239 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-22-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[I.D. 101399A]

#### Pelagics Fisheries of the Western Pacific Region

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

**ACTION:** Notice of Intent to prepare an Environmental Impact Statement (EIS); Notice of Intent to prepare an Environmental Assessment (EA); scoping meetings; request for comments.

**SUMMARY:** On October 6, 1999, NMFS announced its intent to prepare an EIS on Federal management of the fishery for pelagic species in the exclusive economic zone (EEZ) waters of the Western Pacific Region. The scope of the EIS analysis will include all activities related to the conduct of the fishery authorized and managed under the Fishery Management Plan for the Pelagic Fisheries of the Western Pacific Region (FMP) and all amendments thereto. Additionally, NMFS announced its intention to prepare an EA on the fishery for pelagic species in the EEZ waters of the Western Pacific Region. The scope of the analysis of the EA will include all activities related to the conduct of the fishery for the 2-year period NMFS anticipates is necessary to

prepare the EIS. Both the EIS and EA will examine the impacts of pelagics harvest on, among other things, sea turtles and seabirds.

NMFS will hold concurrent scoping meetings to provide for public input into the range of actions, alternatives, and impacts that the EIS and EA should consider. Scoping for the EIS and EA commenced with publication of the document published on October 6, 1999. In addition to holding the scoping meetings, NMFS is accepting written comments on the range of actions, alternatives, and impacts it should be considering for this EIS, as well as comments on the scope of the EA.

**DATES:** Written comments will be accepted through December 6, 1999. See ADDRESSES for location to mail written comments. See SUPPLEMENTARY INFORMATION for meeting times and special accommodations.

**ADDRESSES:** Written comments and requests to be included on a mailing list of persons interested in the EIS should be sent to Marilyn Luipold, Pacific Islands Area Office, NMFS, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814-4700.

See SUPPLEMENTARY INFORMATION for meeting locations and special accommodations.

**FOR FURTHER INFORMATION CONTACT:** Marilyn Luipold, 808-973-2937 or 2935 extension 204.

**SUPPLEMENTARY INFORMATION:** Under the Magnuson-Stevens Fishery Conservation and Management Act, the United States has exclusive fishery management authority over all living marine resources within the EEZ between the seaward boundary of each state or U.S. island possession seaward to 200 nautical miles from the baseline used to measure the territorial sea. The management of these marine resources is vested in the Secretary of Commerce and in eight regional fishery management councils. The Western Pacific Fishery Management Council (Council) has the responsibility to prepare FMPs for the marine resources that require conservation and management in the Western Pacific Region. The National Environmental Policy Act (NEPA) requires preparation of EISs for major Federal actions significantly impacting the quality of the human environment (40 CFR 1502.9(a)).

The FMP was developed by the Council, and regulations implementing management measures were published on February 17, 1987 (52 FR 5983). An EA was prepared for the action implementing the FMP. The FMP has been amended seven times, and NEPA



environmental documents (environmental assessments, categorical exclusions, findings of no significant impact, and an EIS) have been prepared for each FMP and regulatory amendment. However, many of these earlier documents have become outdated and/or focused on individual management actions, making it difficult to obtain a comprehensive view of issues and management options for the fishery as it exists today. NMFS is undertaking preparation of a comprehensive EIS in order to analyze the fishery as it is currently conducted, to address any and all impacts that might have been overlooked in earlier analyses, and to improve management of the fishery. The Federal action under review is defined as, among other things, all activities authorized and managed under the FMP, as amended.

The EIS will present an overall picture of the environmental effects of fishing as conducted under the FMP, rather than focusing narrowly on one management action, and will include a range of reasonable management alternatives and an analysis of their impacts in order to define issues and provide a clear basis for choice among options by the public, the Council, and NMFS. NMFS intends to assess the biological and socio-economic impacts that result from regulation of the pelagic fisheries of the Western Pacific Region, including license limitation, as well as present and potential controls on effort, harvest levels, location, timing, and methods of fishing. The effects on associated species, including interactions with protected species, will be assessed. NMFS intends to evaluate the significant changes that have occurred in the pelagic fisheries, including the significant cumulative effects of changes in fishing activities, socio-economics, the environment, and management. The assessment will include analysis of the cumulative or incremental impacts of actions and alternatives. Impacts associated with status quo management (i.e., continuation of fishing as currently conducted) will be presented and compared to situations simulating limits on fishing areas and/or gears over all or parts of the management area. Possible alternatives to the current conduct of the fishery include a range of area and/or seasonal closures for the longline fishery, gear restrictions and/or modifications, including prohibitions on the use of longline gear in some or all of the management area, and adjustments to requirements for handling incidental hookings and takings of protected species. The

impacts of EEZ fishing activity and harvest on the marine environment will be assessed under representative alternative management scenarios that will ensure consideration of impacts that may reach beyond the EEZ. As the number of possible alternatives is virtually infinite, the EIS will not consider detailed alternatives for every aspect of the FMP. Therefore, a principal objective of the scoping and public input process is to identify a reasonable set of management alternatives that, with adequate analysis, will sharply define critical issues and provide a clear basis for choice among the alternatives.

#### Issues

The environmental consequences section of the EIS will display the impacts of pelagics harvest accruing with present management regulations and under a range of representative alternative management regulations on Western Pacific ecosystem issues. These issues include: Essential fish habitat (EFH), target and non-target species of fish (including tunas, swordfish, and sharks), fish that are discarded, marine mammals (Hawaiian monk seals and cetaceans), sea turtles, and seabirds present in the Western Pacific ecosystem. In addition, the environmental consequences section will contain a summary, interpretation, and predictions for socio-economic issues associated with conduct of the fishery on the following groups of individuals: (1) Those who participate in harvesting the fishery resources and other living marine resources, (2) those who process and market the fish and fishery products, (3) those who are involved in allied support industries, (4) those who consume fishery products, (5) those who rely on living marine resources in the management area either for subsistence needs or for recreational benefits, (6) those who benefit from non-consumptive uses of living marine resources, (7) those involved in managing and monitoring fisheries, and (8) fishing communities.

#### EA Issues

In the EA, NMFS intends to evaluate whether the conduct of the current fisheries over the next 2 years will have significant environmental impacts. The Federal action under review in the EA is defined as all activities authorized and managed under the FMP, as amended, for the 2-year period anticipated to be necessary for preparation of the EIS. The EA will present an overall picture of the environmental effects over the next 2 years of fishing as conducted under the

FMP. Efforts will be made to quantify and explain the intensity of projected impacts on EFH, target and non-target species of fish (including tunas, swordfish, and sharks), fish that are discarded, marine mammals (Hawaiian monk seals and cetaceans), sea turtles, and seabirds present in the Western Pacific ecosystem. Additionally, the EA will evaluate socio-economic impacts associated with the fishery on groups of individuals, including fishing communities, harvesters, processors and marketers, consumers, subsistence and recreational users of living marine resources in the management area, non-consumptive users, and individuals involved in allied support industries and management and monitoring of the fisheries. Although the focus of the EA will be analysis of impacts associated with continuation of fishing as currently conducted, reasonable alternatives for application in the 2-year period, including area and/or seasonal closures for the longline fishery, gear restrictions and/or modifications including prohibitions on the use of longline gear in part or all of the management area, and adjustments to requirements for handling incidental hookings and takings of protected species, will be addressed.

#### Public Involvement

Scoping for the EIS and EA began with publication of the document on October 6, 1999, at 64 FR 54272. Informational presentations of the project will be made at scoping meetings held in the Hawaiian Islands on Oahu, Kauai, Maui, and Hawaii. at the following times and locations:

#### Dates and Times

1. Lihue, Kauai, HI—October 25, 1999, 6 - 8 p.m., Outrigger Kauai Beach Hotel, 4331 Kauai Beach Dr., Lihue, HI 96766.

2. Kona, Hawaii, HI—October 27, 1999, 6 - 8 p.m., Hotel King Kamehameha, 75-5660 Palani Rd., Kailua Kona, HI 96740 3. Hilo, Hawaii, HI—October 28, 1999, 6 - 8 p.m., Hawaii Naniloa Resort, 93 Banyan Dr., Hilo, HI 96720

4. Kihei, Maui, HI—November 4, 1999, at 6 - 8 p.m., Maui Coast Hotel, 2259 South Kihei Rd., Kihei, HI 96753.

5. Haleiwa, Oahu, HI—November 8, 1999, 6 - 8 p.m., Haleiwa Alii Beach Park, 66167 Haleiwa Rd., Haleiwa, HI 96712.

6. Wai'anai, Oahu, HI -- November 30, 1999, 6 - 8 p.m., Wai'anai Public Library, 85625 Farrington Hwy., Wai'anai, HI 96792 Arrangements are being made for meetings to be held on or about November 15, 1999, in Pago Pago,

American Samoa; November 17, 1999, in Saipan, Commonwealth of the Northern Mariana Islands; and November 18, 1999, in Tumon Bay, Guam. Specific times and locations will be announced in a separate **Federal Register** document. The Responsible Program Manager for this EIS is Rodney R. McInnis, Acting Southwest Regional Administrator, NMFS.

#### Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Marilyn Luipold, (see **ADDRESSES**),

808-973-2937 (voice) or 808-973-2941 (fax), at least 5 days before the meeting date.

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

Dated: October 14, 1999.

**Bruce C. Morehead,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27354 Filed 10-15-99; 3:22 pm]

BILLING CODE 3510-22-F

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 990304062-9062-01; I.D. 101499A]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 620 of the Gulf of Alaska

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

**ACTION:** Inseason adjustment; request for comments.

**SUMMARY:** NMFS issues an inseason adjustment opening the D fishing season for pollock in Statistical Area 620 of the Gulf of Alaska (GOA) for 36 hours. This adjustment is necessary to manage the D seasonal allowance of the pollock total allowable catch (TAC) in Statistical Area 620 of the GOA.

**DATES:** Effective 1200 hrs, A.l.t., October 14, 1999, until 2400 hrs, A.l.t., October

15, 1999. Comments must be received at the following address no later than 4:30 p.m., A.l.t., October 29, 1999.

**ADDRESSES:** Comments may be mailed to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668, Attn: Lori Gravel. Hand delivery or courier delivery of comments may be sent to the Federal Building, 709 West 9th Street, Room 453, Juneau, AK 99801.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 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.

NMFS issued a prohibition on directed fishing for pollock effective October 12, 1999, for Statistical Area 620, in accordance with § 679.20(d)(1)(iii), which was filed with the Office of the Federal Register on October 12, 1999.

As of October 13, 1999, 3,500 metric tons (mt) of pollock remain in the D seasonal allowance of the pollock TAC in Statistical Area 620 of the GOA. Section 679.23(b) specifies that the time of all openings and closures of fishing seasons other than the beginning and end of the calendar fishing year is 1200 hrs, A.l.t. Current information shows the catching capacity of vessels catching pollock for processing by the inshore component in Statistical Area 620 of the GOA is in excess of 3,000 mt per day. The Administrator, Alaska Region, NMFS, has determined that the D seasonal allowance of the pollock TAC could be exceeded if a 48-hour fishery were allowed to occur. NMFS intends that the seasonal allowance not be exceeded and, therefore, will not allow a 48-hour directed fishery. NMFS, in accordance with § 679.25(a)(1)(i), is

adjusting the D fishing season for pollock in Statistical Area 620 of the GOA by closing the fishery at 2400 hrs, A.l.t., October 15, 1999, at which time directed fishing for pollock will be prohibited. This action has the effect of opening the fishery for 36 hours. NMFS is taking this action to allow a controlled fishery to occur, thereby preventing the overharvest of the D seasonal allowance of the pollock TAC designated in accordance with the Emergency Interim Rule establishing Steller sea lion protection measures for pollock off Alaska. In accordance with § 679.25(a)(2)(iii), NMFS has determined that prohibiting directed fishing at 2400 hrs, A.l.t., October 15, 1999, after a 36 hour opening is the least restrictive management adjustment to achieve the D seasonal allowance of the pollock TAC and will allow other fisheries to continue in noncritical areas and time periods. Pursuant to § 679.25(b)(2), NMFS has considered data regarding catch per unit of effort and rate of harvest in making this adjustment.

#### Classification

The Assistant Administrator for Fisheries, NOAA, finds for good cause that providing prior notice and public comment or delaying the effective date of this action is impracticable and contrary to the public interest. Without this inseason adjustment, NMFS could not allow the D seasonal allowance of the pollock TAC in Statistical Area 620 of the GOA to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until October 29, 1999.

This action is required by §§ 679.20 and 679.25 and is exempt from review under E.O. 12866.

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

Dated: October 14, 1999.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. 99-27298 Filed 10-14-99; 4:33 pm]

BILLING CODE 3510-22-F

# Notices

Federal Register

Vol. 64, No. 202

Wednesday, October 20, 1999

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request—Child Nutrition Labeling Program

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

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Food and Nutrition Service to request Office of Management and Budget review of information collection activities related to the Child Nutrition Labeling Program.

**DATES:** Comments on this notice must be received by December 20, 1999.

**ADDRESSES:** Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (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. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval, and will become a matter of public record. Send comments to: Ms. Lori French, Branch Chief, Nutrition Promotion and Training Branch, Child Nutrition Division, Food and Nutrition Service, United States

Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

**FOR FURTHER INFORMATION CONTACT:** Request for additional information or copies of the information collection instruments and instruction should be directed to Marion Hinnners at (703) 305-2621.

#### SUPPLEMENTARY INFORMATION:

*Title:* Child Nutrition Labeling Program.

*OMB Number:* 0584-0320.

*Expiration Date:* 9/30/99.

*Type of Request:* Revision of currently approved, voluntary collection of information contained in existing regulation.

*Abstract:* The Child Nutrition (CN) Labeling Program is a voluntary technical assistance program to aid schools and institutions participating in the National School Lunch Program (NSLP), School Breakfast Program (SBP), Child and Adult Care Food Program (CACFP), and Summer Food Service Program (SFSP) in determining the contribution a commercial product makes toward the food-based meal pattern requirements of these programs. There is no Federal requirement that commercial products must have a CN label statement.

To participate in the Child Nutrition Labeling Program, industry submits product labels and formulations to the Food and Nutrition Service (FNS) that are in conformance with the Food Safety and Inspection Service (FSIS) label approval program for meat and poultry, or United States Department of Commerce (USDC) label approval program for seafood products. FNS reviews a manufacturer's product formulation to determine the contribution a serving of the product makes toward the food-based meal pattern requirements. The application form submitted to FNS is the same application that companies submit to FSIS or USDC to receive label approval. A CN label application is also reviewed by FNS for accuracy.

*Estimate of Burden:* Based on our most recent interviews with manufacturers it is estimated that it takes a manufacturer forty-five minutes to complete the required calculations and to formulate the CN label application.

*Respondents:* Participation in the CN labeling program is voluntary. Only manufacturers who wish to place CN

labels on their products must comply with program requirements. Last year 795 possible establishments sent in 4163 label transmittals.

*Estimated Number of Respondents:* 795

*Estimated Number of Responses per Respondent:* 5.2.

*Estimated Total Annual Burden on Respondents:* 3122.25 hours.

Dated: October 12, 1999.

**Samuel Chambers, Jr.,**

*Administrator, Food and Nutrition Service.*

[FR Doc. 99-27404 Filed 10-19-99; 8:45 am]

BILLING CODE 3410-30-P

## ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

### Public Rights-of-Way Access Advisory Committee; Meeting

**AGENCY:** Architectural and Transportation Barriers Compliance Board.

**ACTION:** Notice of appointment of advisory committee members and date of first meeting.

**SUMMARY:** The Architectural and Transportation Barriers Compliance Board (Access Board) has decided to establish an advisory committee to assist it in developing a proposed rule on accessibility guidelines for newly constructed and altered public rights-of-way covered by the Americans with Disabilities Act of 1990 and the Architectural Barriers Act of 1968. The Public Rights-of-Way Access Advisory Committee (Committee) includes organizations which represent the interests affected by the accessibility guidelines for public rights-of-way. This notice also announces the times and location of the first Committee meeting, which will be open to the public.

**DATES:** The first meeting of the Committee is scheduled for November 29 and 30, 1999, beginning at 9:00 a.m. and ending at 5:00 p.m. each day.

**ADDRESSES:** The meeting will be held in the 3rd floor training room at 1331 F Street, NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Scott Windley, Office of Technical and Information Services, Architectural and

Transportation Barriers Compliance Board, 1331 F Street, NW., suite 1000, Washington, DC, 20004-1111. Telephone number (202) 272-5434 extension 125 (Voice); (202) 272-5449 (TTY). E-mail [windley@access-board.gov](mailto:windley@access-board.gov). This document is available in alternate formats (cassette tape, Braille, large print, or computer disk) upon request. This document is also available on the Board's Internet Site (<http://www.access-board.gov/notices/prowapt.htm>).

**SUPPLEMENTARY INFORMATION:** On August 12, 1999, the Architectural and Transportation Barriers Compliance Board (Access Board) published a notice of intent to establish an advisory committee to provide recommendations for developing a proposed rule addressing accessibility guidelines for newly constructed and altered public rights-of-way covered by the Americans with Disabilities Act of 1990 and the Architectural Barriers Act of 1968. 64 FR 43980 (August 12, 1999).

The notice identified the interests that are likely to be significantly affected by the accessibility guidelines: Federal agencies; design professional organizations; transportation and traffic engineering institutes, departments, and organizations; State and local government public works and transportation agencies; pedestrian and bicycle organizations; standard setting organizations; organizations representing the access needs of individuals with disabilities; and other persons affected by the accessibility guidelines.

Over 65 nominations were submitted. Approximately 20 nominations were received from organizations representing persons with disabilities. About 10 other nominations were received from individuals (or family members of) persons with disabilities. The remaining nominations primarily consisted of organizations representing the transportation, design, and engineering industry which includes some State and local government departments of transportation.

For the reasons stated in the notice of intent, the Access Board has determined that establishing the Public Right-of-Way Access Advisory Committee (Committee) is necessary and in the public interest. The Access Board has appointed 29 members to the Committee from the following organizations:

America Walks  
American Association of State Highway and Transportation Officials  
American Council of the Blind  
American Institute of Architects  
American Public Transit Association

American Public Works Association  
Association for Education and Rehabilitation of the Blind and Visually Impaired  
Californians for Disability Rights  
Canadian Standards Association, Technical Committee on Barrier-Free Design  
City of Birmingham, Department of Planning, Engineering and Permits  
Disability and Business Technical Assistance Centers  
Disability Rights Education and Defense Fund  
Hawaii Commission on Persons With Disabilities  
Hawaii Department of Transportation  
Institute of Transportation Engineers  
Los Angeles Department of Public Works, Bureau of Street Services  
Massachusetts Architectural Access Board  
Municipality of Anchorage  
National Council on Independent Living  
National Federation of the Blind  
New York State Department of Transportation  
Paralyzed Veterans of America  
Portland Office of Transportation  
San Francisco Mayor's Office on Disability  
State of Alaska  
TASH  
Texas Department of Transportation  
The Seeing Eye  
U.S. Department of Transportation, Federal Highway Administration

The Access Board regrets being unable to accommodate all requests for membership on the Committee. In order to keep the Committee to a size that can be effective, it was necessary to limit membership. It is also desirable to have balance among members of the Committee representing different clusters of interest, such as disability organizations and the transportation industry. The Committee membership identified above provides representation for each interest effected by issues to be discussed.

Committee meetings will be open to the public and interested persons can attend the meetings and communicate their views. Members of the public will have an opportunity to address the Committee on issues of interest to them and the Committee. Members of groups or individuals who are not members of the Committee may also have the opportunity to participate with subcommittees on the Committee. The Access Board believes that participation of this kind can be very valuable for the advisory committee process.

Additionally, all interested persons will have the opportunity to comment when the proposal accessibility guidelines for

public rights-of-way are issued in the **Federal Register** by the Access Board.

The meeting will be help at a site accessible to individuals with disabilities. Individuals who require sign language interpreters or real-time captioning systems should contact Scott Windley by November 12, 1999.

Decisions with respect to future meetings will be made at the first meeting. Notices of future meetings will be published in the **Federal Register**.

**Lawrence W. Roffee,**

*Executive Director.*

[FR Doc. 99-27329 Filed 10-19-99; 8:45 am]

BILLING CODE 8150-01-M

## DEPARTMENT OF COMMERCE

### Bureau of Export Administration

#### Action Affecting Export Privileges; Thane-Coat, Inc.

In the Matters of: Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477, Jerry Vernon Ford, President, Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477 and with an address at 7707 Augustine Drive, Houston, Texas 77036, and Preston John Engebretson, Vice-President, Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477 and with an address at 8903 Bonhomme Road, Houston, Texas 77074, Respondents.

#### Decision and Order on Renewal of Temporary Denial Order

On April 20, 1999, I issued a Decision and Order on Renewal of Temporary Denial Order (hereinafter "Order" or "TDO"), renewing for 180 days, in a "non-standard" format, a May 5, 1997 Order naming, *inter alia*, Thane-Coat, Inc.; Jerry Vernon Ford, president, Thane-Coat, Inc.; and Preston John Engebretson, vice-president, Thane-Coat, Inc. (hereinafter referred to collectively as the "Respondents"), as persons temporarily denied all U.S. export privileges. 64 FR 23051-23052 (April 29, 1999). Unless renewed, the Order will expire on October 16, 1999.

On September 24, 1999, pursuant to § 766.24 of the Export Administration Regulations (currently codified at 15 CFR parts 730-774 (1999)) (hereinafter the "Regulations"), issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C.A. app. sections 2401-2420 (1991 & Supp. 1999)) (hereinafter the "Act"),<sup>1</sup> the Office of

<sup>1</sup> The Act expired on August 20, 1994. Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 CFR, 1995 Comp. 501 (1996)), August 14, 1996 (3 CFR, 1996 Comp. 298 (1997)), August 13, 1997

Export Enforcement, Bureau of Export Administration, United States Department of Commerce (hereinafter "BXA"), requested that I renew the Order against Thane-Coat, Inc., Jerry Vernon Ford, and Preston John Engebretson for 180 days in a non-standard format, consistent with the terms agreed to by and between the parties in April 1998.

In its request, BXA stated that, as a result of an ongoing investigation, it had reason to believe that, during the period from approximately June 1994 through approximately July 1996, Thane-Coat, Inc., through Ford and Engebretson, and using its affiliated companies, TIC Ltd. and Export Materials, Inc., made approximately 100 shipments of U.S.-origin pipe coating materials, machines, and parts to the Dong Ah Consortium in Benghazi, Libya. These items were for use in coating the internal surface of prestressed concrete cylinder pipe for the Government of Libya's Great Man-Made River Project.<sup>2</sup> Moreover, BXA's investigation gave it reason to believe that the Respondents and the affiliated companies employed a scheme to export U.S.-origin products from the United States, through the United Kingdom, to Libya, a country subject to a comprehensive economic sanctions program, without the authorizations required under U.S. law, including the Regulations. The approximate value of the 100 shipments at issue was \$35 million. In addition, the Respondents and the affiliated companies undertook several significant and affirmative actions in connection with the solicitation of business on another phase of the Great Man-Made River Project.

BXA has stated that it believes that the matters under investigation and the information obtained to date in that investigation support renewal of the TDO issued against the Respondents. In that regard, in April, 1998 BXA and the Respondents reached an agreement, whereby BXA sought a renewal of the TDO in a "non-standard" format, denying all of the Respondents' U.S. export privileges to the United Kingdom, the Bahamas, Libya, Cuba,

Iraq, North Korea, Iran, and any other country or countries that may be made subject in the future to a general trade embargo by proper legal authority. In return, the Respondents agreed that, among other conditions, at least 14 days in advance of any export that any of the Respondents intends to make of any item from the United States to any destination world-wide, the Respondents will provide to BXA's Dallas Field Office (i) notice of the intended export, (ii) copies of all documents reasonably related to the subject transaction, including, but not limited to, the commercial invoice and bill of lading, and (iii) the opportunity, during the 14-day notice period, to inspect physically the item at issue to ensure that the intended shipment is in compliance with the Export Administration Act, the Export Administration Regulations, or any order issued thereunder. BXA has sought renewal of the TDO in a "non-standard" format; respondents have not opposed renewal of the TDO in the "non-standard" format.

Based on BXA's showing, I find that it is appropriate to renew the order temporarily denying the export privileges of Thane-Coat, Inc., Jerry Vernon Ford, and Preston John Engebretson in a "non-standard" format, incorporating the terms agreed to by and between the parties in April 1998. I find that such renewal is necessary in the public interest to prevent an imminent violation of the Regulations and to give notice to companies in the United States and abroad to cease dealing with these persons in any commodity, software, or technology subject to the Regulations and exported or to be exported to the United Kingdom, the Bahamas, Libya, Cuba, Iraq, North Korea, Iran, and any other country or countries that may be made subject in the future to a general trade embargo by proper legal authority, or in any other activity subject to the Regulations with respect to these specific countries. Moreover, I find such renewal is in the public interest in order to reduce the substantial likelihood that Thane-Coat, Inc., Ford and Engebretson will engage in activities which are in violation of the Regulations.

Accordingly, *it is therefore ordered:*

First, that Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477, and all of its successors or assigns, officers, representatives, agents, and employees when acting on its behalf, Jerry Vernon Ford, President, Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477, and 7707 Augustine Drive, Houston, Texas 77036, and all of his successors, or assigns, representatives, agents and employees when acting on his behalf,

and Preston John Engebretson, Vice President, Thane-Coat, Inc., 12725 Royal Drive, Stafford, Texas 77477 and 8903 Bonhomme Road, Houston, Texas 77074, and all of his successors, or assigns, representatives, agents, and employees when acting on his behalf (all of the foregoing parties hereinafter collectively referred to as the "denied persons"), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") subject to the Export Administration Regulations (hereinafter the "Regulations") and exported or to be exported from the United States to the United Kingdom, the Bahamas, Libya, Cuba, Iraq, North Korea, or Iran, or to any other country or countries that may be made subject in the future to a general trade embargo pursuant to proper legal authority (hereinafter the "Covered Countries"), or in any other activity subject to the Regulations with respect to the Covered Countries, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item that is subject to the Regulations and that is exported or to be exported from the United States to any of the Covered Countries, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States to any of the Covered Countries that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of any of the denied persons any item subject to the Regulations to any of the Covered Countries;

B. Take any action that facilitates the acquisition, or attempted acquisition by any of the denied persons of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States to any of the Covered Countries, including financing or other support activities related to a transaction whereby any of the denied persons acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted

(3 CFR, 1997 Comp. 306 (1998)), August 13, 1998 (3 CFR, 1998 Comp. 294 (1999)), and August 10, 1999 (64 FR 44101, August 13, 1999), continued the Regulations in effect under the International Emergency Economic Powers Act (currently codified at 50 U.S.C.A. 1701-1706 (1991 & Supp. 1999)).

<sup>2</sup> BXA understands that the ultimate goal of this project is to bring fresh water from wells drilled in southeast and southwest Libya through prestressed concrete cylinder pipe to the coastal cities of Libya. This multiphase engineering endeavor is being performed by the Dong Ah Construction Company of Seoul, South Korea.

acquisition from any of the denied persons of any item subject to the Regulations that has been exported from the United States to any of the Covered Countries;

D. Obtain from any of the denied persons in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States to any of the Covered Countries; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States to any of the Covered Countries, and which is owned, possessed or controlled by any of the denied persons, or service any item, of whatever origin, that is owned, possessed or controlled by any of the denied persons if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States to any of the Covered Countries. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that, at least 14 days in advance of any export that any of the denied persons intends to make of any item from the United States to any destination world-wide, the denied person will provide to BXA's Dallas Field Office (i) notice of the intended export, (ii) copies of all documents reasonably related to the subject transaction, including, but not limited to, the commercial invoice and bill of lading, and (iii) the opportunity, during the 14-day notice period, to inspect physically the item at issue to ensure that the intended shipment is in compliance with the Export Administration Act, the Export Administration Regulations, or any order issued thereunder.

Fourth, that, after notice and opportunity for comment, as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to any of the denied persons by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services, may also be made subject to the provisions of this Order.

Fifth, that this Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

Sixth, that, in accordance with the provisions of § 766.24(e) of the Regulations, Thane-Coat, Ford, or Engebretson may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202-4022.

Seventh, that this Order is effective immediately and shall remain in effect for 180 days.

Eighth, that, in accordance with the provisions of § 766.24(d) of the Regulations, BXA may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. Any respondent may oppose a request to renew this Order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be served on each Respondent and shall be published in the **Federal Register**.

Entered this 13th day of October, 1999.

**F. Amanda DeBusk,**

*Assistant Secretary for Export Enforcement.*

[FR Doc. 99-27402 Filed 10-19-99; 8:45 am]

BILLING CODE 3510-DT-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

#### Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with § 351.213 of the Department of Commerce (the Department) Regulations (19 CFR 351.213 (1997)), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

#### Opportunity To Request a Review

Not later than the last day of October 1999, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

	Period
<b>Antidumping Duty Proceedings</b>	
Italy: Pressure Sensitive Tape, A-475-059 .....	10/1/98-9/30/99
Japan:	
Steel Wire Rope, A-588-045 .....	10/1/98-9/30/99
Tapered Roller Bearings, Over 4 Inches, A-588-604 .....	10/1/98-9/30/99
Tapered Roller Bearings, Under 4 Inches, A-588-054 .....	10/1/98-9/30/99
Vector Supercomputers, A-588-841 .....	10/1/98-9/30/99
Malaysia: Extruded Rubber Thread, A-557-805 .....	10/1/98-9/30/99
People's Republic of China:	
Barium Chloride, A-570-007 .....	10/1/98-9/30/99
Lock Washers, A-570-822 .....	10/1/98-9/30/99
Shop Towels, A-570-003 .....	10/1/98-9/30/99
Yugoslavia: Industrial Nitrocellulose, A-479-801 .....	10/1/98-9/30/99
<b>Countervailing Duty Proceedings</b>	
Brazil: Certain Agricultural Tillage Tools, C-351-406 .....	1/1/98-12/31/98
Colombia: Textile & Textile Products, C-301-401 .....	1/1/98-12/31/98
India: Iron Metal Castings, C-533-063 .....	1/1/98-12/31/98
Iran: Roasted In-Shell Pistachios, C-507-601 .....	1/1/98-12/31/98
Sweden: Certain Carbon Steel Products, C-401-401 .....	1/1/98-12/31/98

	Period
<b>Suspension Agreements</b>	
Kyrgyzstan: Uranium, A-835-802 .....	10/1/98-9/30/99
Russia: Uranium, A-821-802 .....	10/1/98-9/30/99
Uzbekistan: Uranium, A-844-802 .....	10/1/98-9/30/99

In accordance with § 351.213 of the regulations, an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. The Department changed its requirements for requesting reviews for countervailing duty orders. Pursuant to 771(9) of the Act, an interested party must specify the individual producers or exporters covered by the order or suspension agreement for which they are requesting a review (Department of Commerce Regulations, 62 FR 27295, 25494 (May 19, 1997)). Therefore, for both antidumping and countervailing duty reviews, the interested party must specify for which individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with § 351.303(f)(1)(i) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of "Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation" for requests received by the last day of October 1999. If the Department does not receive, by the last

day of October 1999, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute but is published as a service to the international trading community.

Dated: October 15, 1999.

**Bernard T. Carreau,**

*Deputy Assistant Secretary for Group II, AD/CVD Enforcement.*

[FR Doc. 99-27411 Filed 10-19-99; 8:45 am]

BILLING CODE 3510-DS-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

[I.D. 101399E]

#### Mid-Atlantic Fishery Management Council and the New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice of joint public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council and the New England Fishery Management Council Joint Dogfish Committee, together with the Joint Dogfish Industry Advisory Panel, will hold a public meeting.

**DATES:** The meeting will be held on Wednesday, November 3, 1999, from 10:00 a.m. until 4:00 p.m.

**ADDRESSES:** This meeting will be held at the Holiday Inn Boston Logan Airport, 225 McClellan Highway, Boston, MA; telephone: 617-569-5250.

*Council address:* Mid-Atlantic Fishery Management Council, Room 2115, 300 S. New Street, Dover, DE 19904 and New England Fishery Management

Council, 5 Broadway, Saugus, MA 01906.

#### FOR FURTHER INFORMATION CONTACT:

Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council; telephone: 302-674-2331, ext. 19, or Paul Howard, Executive Director, New England Fishery Management Council; telephone: 781-231-0422.

**SUPPLEMENTARY INFORMATION:** The purpose of this meeting is to review the results of the recent Dogfish Technical Committee meeting and to develop quota and management measures for spiny dogfish for the 2000-01 fishing year including quotas, trip limits, and any other measure specified in the fishery management plan. The joint committee will also discuss the NMFS partial disapproval of the Spiny Dogfish FMP and possible alternatives for female biomass rebuilding.

Although non-emergency issues not contained in this agenda may come before the Committee for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, such issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

#### Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Joanna Davis at the Council Office (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: October 15, 1999.

**Richard W. Surdi,**

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

[FR Doc. 99-27420 Filed 10-19-99; 8:45 am]

BILLING CODE 3510-22-F



**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

[I.D. 101399F]

**New England Fishery Management Council; Public Meetings**

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

**ACTION:** Notice of public meetings.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling public meetings of its Scientific and Statistical Committee, Social Sciences Advisory Committee, Habitat Committee and Advisory Panel, Groundfish Committee and Advisory Panel, Sea Scallop Committee and Advisory Panel, Gear Conflict Committee and Enforcement Committee in November, 1999 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from these groups will be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** The meetings will be held between Thursday, November 4, 1999 and Monday, November 15, 1999. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

**ADDRESSES:** The meetings will be held in, Saugus, Peabody and Danvers, MA. See **SUPPLEMENTARY INFORMATION** for specific locations.

**FOR FURTHER INFORMATION CONTACT:** Paul J. Howard, Executive Director, New England Fishery Management Council; (781) 231-0422.

**SUPPLEMENTARY INFORMATION:****Meeting Dates and Agendas**

*Monday, November 4, 1999, 10 a.m. and Friday, November 5, 8:30 a.m.—*Scientific and Statistical Committee Meeting

Location: New England Fishery Management Council Office, 5 Broadway, Saugus, MA 01906; telephone: (781) 231-0422.

The committee will evaluate the scientific information and analyses used in the Northeast Multispecies Stock Assessment and Fishery Evaluation (SAFE) Report. The SAFE report will include the Multispecies Monitoring Committee Report which addresses the status of the multispecies finfish stocks, evaluates the effectiveness of management measures and estimates the potential impacts of possible management options that could be used to adjust the Northeast Multispecies

Fishery Management Plan (FMP) for the 2000-01 fishing year.

*Friday, November 5, 1999, 10 a.m.—*Social Sciences Advisory Committee Meeting

The committee will finalize recommendations concerning improvements to the economic, social and community impact analyses in Council documents and review the SAFE Reports for the Scallop and the Northeast Multispecies fisheries. Any recommendations made at the last committee meeting will be revisited at this meeting for purposes of ensuring adequate public comment.

*Tuesday, November 9, 1999, 9:30 a.m.—*Joint Habitat Committee and

Advisory Panel Meeting  
Location: Sheraton Ferncroft Hotel, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777-2500.

The committee will review proposals for scallop fishing access to three groundfish closed areas (Closed Areas I and II on Georges Bank, and the Nantucket Lightship Closed Area). The committee will develop recommendations on this issue and also will discuss the NMFS "internal" Essential Fish Habitat consultation process.

*Wednesday, November 10, 1999, 9:30 a.m.—*Joint Groundfish Committee and Groundfish Advisory Panel Meeting

Location: Sheraton Ferncroft Hotel, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777-2500.

The committee and panel will review the Northeast Multispecies SAFE Report, including the annual Multispecies Monitoring Committee Report and proposals from industry for management measures to be considered for the 2000-01 fishing year. The committee may recommend a preferred alternative to the Council for the Northeast Multispecies Plan annual framework adjustment. The committee and panel also will discuss proposals to allow scallop dredge vessel access to Closed Areas I and II and the Nantucket Lightship Closed Area, and may develop recommendations to the Council for measures to be included in the Northeast Multispecies FMP annual framework adjustment.

*Friday, November 12, 1999, 9:30 a.m.—*Joint Scallop Committee and

Scallop Advisory Panel Meeting  
Location: Sheraton Ferncroft Hotel, 50 Ferncroft Road, Danvers, MA 01923; telephone: (978) 777-2500.

The committee will review the impacts of the proposed annual framework adjustment alternatives for the Scallop FMP and will recommend a preferred management option to the Council at its November 16-18, 1999 meeting. Final action on the framework

adjustment is scheduled to occur at that time.

As an addition to the committee agenda, members will discuss and recommend changes to the Sea Scallop Total Allowable Catch research set-aside mechanism that is currently in the Sea Scallop FMP.

*Monday, November 15, 1999, 9:30 a.m.—*Gear Conflict Committee Meeting

Location: New England Fishery Management Council Office, 5 Broadway, Saugus, MA 01906; telephone: (781) 231-0422.

The committee will develop recommendations concerning gear conflict issues to be considered by the Council when considering scallop vessel access to Closed Areas I and II on Georges Bank, and the Nantucket Lightship Closed Area. The committee also may discuss other gear conflict issues that are brought to its attention.

*Monday, November 15, 1999, 1 p.m.—*Enforcement Committee Meeting

Location: New England Fishery Management Council Office, 5 Broadway, Saugus, MA 01906; telephone: (781) 231-0422.

The committee will develop recommendations concerning enforcement issues related to scallop vessel access to Closed Areas I and II on Georges Bank, and the Nantucket Lightship Closed Area for the fishing year March-February, 2000-01. The committee may discuss other enforcement issues that are brought to its attention.

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 these meetings. 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 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 Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: October 15, 1999.

**Richard W. Surdi,**

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

[FR Doc. 99-27421 Filed 10-19-99; 8:45 am]

BILLING CODE 3510-22-F



**DEPARTMENT OF COMMERCE****Patent and Trademark Office****Performance Review Board**

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Announcement of membership of the Patent and Trademark Office Performance Review Board.

**SUMMARY:** In conformance with the Civil Service Reform Act of 1978, 5 U.S.C. 4314(c)(4), the Patent and Trademark Office announces the appointment of persons to serve as members of its Performance Review Board.

**ADDRESSES:** Comments should be addressed to Director, Office of Human Resources, Patent and Trademark Office, One Crystal Park, Suite 707, Washington, DC 20231.

**FOR FURTHER INFORMATION CONTACT:** Alethea Long-Green at the above address or telephone (703) 305-8062.

**SUPPLEMENTARY INFORMATION:** The membership of the Patent and Trademark Office Performance Review Board is as follows:

Stephen C. Browning, Chair, Acting Associate Commissioner and Chief Financial Officer, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2001

Janice A. Howell, Director, Patent Examining Group, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2001

Jin F. Ng, Director, Patent Examining Group, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2000

Albin F. Drost, Acting Solicitor, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2001

Robert M. Anderson, Deputy Assistant Commissioner for Trademarks, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2001

Gerald R. Lucas, Director, Eastern Administrative Support Center, Department of Commerce, Norfolk, VA 23510, Term—expires September 30, 2001

Robert F. Kugelman, Director, Office of Budget, Department of Commerce, Washington, DC 20230, Term—expires September 30, 2001

H. Dieter Hoinkes, Deputy Administrator for Legislative and International Affairs, Patent and Trademark Office, Washington, DC 20231, Term—expires September 30, 2001

Dated: October 7, 1999.

**Q. Todd Dickinson,**

*Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks.*

[FR Doc. 99-27305 Filed 10-19-99; 8:45 am]

**BILLING CODE 3510-16-M**

**DEPARTMENT OF ENERGY****Office of Science; Fusion Energy Sciences Advisory Committee Renewal**

Pursuant to section 14(a)(2)(A) of the Federal Advisory Committee Act (FACA) Pub. L. 92-463, and section 101-6.1015, title 41 Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General Services Administration (GSA), notice is hereby given that the Fusion Energy Sciences Advisory Committee has been renewed for a two-year period beginning October 1999. The Committee will provide advice to the Department on long-range plans, priorities, and strategies for demonstrating the scientific and technological feasibility of fusion energy.

The renewal of the Fusion Energy Sciences Advisory Committee has been determined to be essential to the conduct of the Department's business and in the public interest in connection with the performance of duties imposed upon the Department of Energy by law. The Committee will continue to operate in accordance with the provisions of the FACA, the GSA regulation on Federal Advisory Committee Management, and other directives and instructions issued in implementation of those acts.

Further information regarding this advisory committee can be obtained from Ms. Rachel Samuel at (202) 586-3279.

Issued in Washington, DC on October 8, 1999.

**James N. Solit,**

*Advisory Committee Management Officer.*

[FR Doc. 99-27422 Filed 10-19-99; 8:45 am]

**BILLING CODE 6450-01-P**

**DEPARTMENT OF ENERGY****Bonneville Power Administration****Fish and Wildlife Implementation Plan**

**AGENCY:** Bonneville Power Administration (BPA), Department of Energy (DOE).

**ACTION:** Notice of intent to prepare an environmental impact statement (EIS).

**SUMMARY:** Throughout the Pacific Northwest region there are several

ongoing processes to develop plans and programs for the management, recovery, and mitigation of the Columbia River Basin's fish and wildlife resources. These plans and programs will help to shape a regional fish and wildlife policy direction that will guide BPA's mitigation and recovery efforts, including its funding, for the next decade or more. BPA expects to shift its fish and wildlife spending accordingly. BPA currently funds over 70 percent of the fish and wildlife mitigation and recovery efforts on behalf of the Federal Columbia River Power System (FCRPS). Consequently, BPA has a responsibility to understand the impacts of those efforts and to ensure it can fund them efficiently. Therefore, BPA intends to prepare an EIS that examines the impacts that may arise from implementing one of the fish and wildlife policy directions reflected in the alternatives being considered in the ongoing regional processes. BPA will coordinate the scoping meetings and comment processes for this EIS with the other ongoing regional processes. However, BPA is preparing this EIS for its own purposes, and the EIS is not a predicate for decisions by other Federal agencies.

**DATES:** BPA will establish a 30-day scoping period during which all interested and affected persons and agencies are invited to comment on the scope of BPA's proposed Fish and Wildlife Implementation Plan EIS. Scoping will help BPA ensure that a full range of issues related to the implementation of its fish and wildlife duties are addressed in the EIS, and also will identify significant or potentially significant impacts that may result from implementation of such a new plan. A Notice of Scoping Meeting(s) will be published in the **Federal Register**. That notice will announce the date(s) and location(s) of the scoping meeting(s) and provide specific information on the close of the scoping period.

When completed, the Draft EIS will be circulated for review and comment, and BPA will hold public comment meetings for the Draft EIS. BPA will consider and respond to comments received on the Draft EIS in the Final EIS.

**ADDRESSES:** BPA invites comments and suggestions on the proposed scope of the Draft EIS. Send comment letters, and requests to be placed on the project mailing list, to Communications, Bonneville Power Administration—KC-7, PO Box 12999, Portland, Oregon, 97212. The phone number of the Communications office is 503-230-3478 in Portland; toll-free 1-800-622-4519

outside of Portland. Comments may also be sent to the BPA Internet address: [comment@bpa.gov](mailto:comment@bpa.gov).

**FOR FURTHER INFORMATION, CONTACT:** Charles C. Alton, Project Manager, KEC-4, Bonneville Power Administration, PO Box 3621, Portland, Oregon, 97208-3621; phone number 503-230-5878; fax number 503-230-5699.

**SUPPLEMENTARY INFORMATION:** BPA markets electric power from 29 hydroelectric dams operated by the United States Army, Corps of Engineers (Corps); and the United States Department of the Interior, Bureau of Reclamation (BoR), in the Pacific Northwest (Idaho, Montana, Oregon, and Washington). Part of the power-marketing responsibility includes complying with the laws meant to protect the environment. In the last two decades, BPA has spent over \$2 billion collected from its ratepayers on measures to mitigate and recover fish and wildlife. BPA currently spends approximately \$252 million annually, plus there are lost power opportunities and operational costs.

Under the Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act), BPA has duties: (1) To protect, mitigate, and enhance fish and wildlife adversely affected by the construction and operation of the FCRPS, and (2) to do so in a manner that provides equitable treatment for such fish and wildlife with the other purposes of the FCRPS. Under the Endangered Species Act (ESA), BPA has duties to avoid jeopardy to species listed under ESA and to aid in the recovery of those species. BPA's mitigation and recovery expenditures are typically in fulfillment of these Northwest Power Act and ESA duties.

BPA expects that the entities that help guide its expenditures for mitigation and recovery will recommend changes in BPA's spending regime and programs. These recommendations could include eliminating some current mitigation projects, significantly modifying others, and initiating whole new projects. These changes in priorities may require reexamination of the impacts BPA enables through its fish and wildlife funding. Therefore, BPA is initiating an EIS to study the environmental impacts that may arise from BPA's implementation of the alternatives being considered in the other regional processes currently underway. The EIS will provide a broad-based comparison of the impacts associated with these alternatives.

The first regional process to develop alternatives that may affect the implementation of BPA's fish and

wildlife duties is the Multi-Species Framework Project (Framework) which is managed collaboratively by the Northwest Power Planning Council (States), Federal agencies, and Tribes. The Framework is developing a set of alternatives for future economic and natural resource management of the basin. The EIS will consider the biological, social, and economic effects of those alternatives.

The other major Federal decision-making processes that may affect BPA's fish and wildlife duties are those associated with planning for future operations of the FCRPS, National Forest Planning activities, and plans for operation of fish hatcheries and regulation of fish harvests. Nine Federal agencies are involved in various aspects of these management activities affecting the Columbia River—the National Marine Fisheries Service, the Corps, the BoR, BPA, the Environmental Protection Agency, the Fish and Wildlife Service, the Bureau of Indian Affairs, the Forest Service, and the Bureau of Land Management. BPA is also participating in ESA consultations that will lead to a decision in the year 2000 regarding how to structure and operate the FCRPS. That decision will not be considered in the EIS here being proposed. The National Environmental Policy Act documentation for that decision has already been or is currently being prepared in a separate process.

In addition to the Framework and Federal Caucus processes, there are numerous other actions related to the development and implementation of BPA's fish and wildlife implementation plan. These actions include studies to address water quality issues in the Columbia and Snake Rivers, various salmon restoration plans, and a review of artificial (hatchery) production. Still other processes may be identified during scoping. This EIS will use information from these efforts in its analysis.

#### Need for the EIS

BPA intends to reexamine the assumptions underlying its current fish and wildlife implementation plan. The purpose of the EIS is to compare the status quo implementation plan with alternatives derived from the other regional processes in an attempt to find a better way to achieve greater administrative efficiency, biological effectiveness, and cost-effectiveness while providing health and stability for the environment and economy.

Issued in Portland, Oregon, on October 8, 1999.

**J. A. Johansen,**

*Administrator and Chief Executive Officer.*

[FR Doc. 99-27423 Filed 10-19-99; 8:45 am]

BILLING CODE 6450-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP99-480-002]

#### Texas Eastern Transmission Corporation; Notice of Compliance Filing

October 14, 1999.

Take notice that on October 7, 1999, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following revised tariff sheets to be effective September 23, 1999:

Second Sub Second Revised Sheet No. 456  
Third Revised Sheet No. 462

Texas Eastern states that the sole purpose of this filing is to comply with the Commission's letter order in Docket Nos. RP99-480-000 and 001 dated September 22, 1999 accepting Texas Eastern's August 23, 1999 filing, to include in its tariff a negotiated rates provision pursuant to the Alternative Rates Policy Statement [74 FERC 61,076 (1996)]. Texas Eastern states that the revised tariff sheets modify the net present value evaluations in Sections 3.12(A)(1) and 3.13(E) of the General Terms and Conditions of its tariff as required by the Commission in the September 22, 1999 letter order.

Texas Eastern states that copies of its filing have been mailed to all affected customers and interested state commissions.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protest must be filed as provided in Section 154.210 of the Commission's Regulations. 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 proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at <http://www.ferc.fed.us/online/>

rims.htm (call 202-208-2222 for assistance).

**David P. Boergers,**  
*Secretary.*

[FR Doc. 99-27359 Filed 10-19-99; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. CP98-133-003]

#### Vector Pipeline L.P.; Notice of Amendment

October 14, 1999.

Take notice that on October 4, 1999, Vector Pipeline L.P. (Vector), 2900 421-7th Avenue SW, Calgary, Alberta, Canada T2P 4K9, filed in Docket No. CP98-133-003 an application pursuant to Section 7(c) of the Natural Gas Act for an amendment to its certificate of public convenience and necessity previously issued by the Commission on May 27, 1999, in Docket No. CP98-133-000, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

The Commission's May 27, 1999 order authorized, among other things, the construction and operation of a pipeline from Joilet, Illinois to the U.S.-Canada border near St. Clair, Michigan. Vector states that the May 27, 1999 order also certificated the "Milford" Compressor Station site; although, the Final Environmental Impact Analysis found that either the proposed "Milford" site or "Alternate Site 2", both located in Oakland County, Michigan, would be acceptable as a site for construction of the compressor station.

Specifically, Vector seeks authorization to move the site of the construction of the subject compressor station from the "Milford" site to "Alternate Site 2" (which Vector has re-named as the "Highland" site). Vector states that it has negotiated a purchase agreement for the "Highland" site, thereby obviating the need for eminent domain. Vector further states that shifting the compressor station site from "Milford" to "Highland" does not impair Vector's ability to meet its design requirements, although the shift will result in additional costs that will increase Vector's recourse rate by approximately \$0.002 per Dth on a unit basis.

Vector also requests that Ordering Paragraph (E) of the May 27, 1999 order be amended to impose the two-year

construction completion/in-service condition, as it applies to this amended compressor station site, from the date of the final order on this amendment application.

Any question regarding this amendment should be directed to Ned Hengerer, Counsel for Vector Pipeline L.P., John & Hengerer, 1200 17th Street, NW, Suite 600, Washington, DC 20036 at (202) 429-8811.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 28, 1999, file with the Federal Energy Regulatory Commission, 888 First Street, NW, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. The Commission's rules require that protestors provide copies of their protests to the party or parties directly involved. Any person wishing to become a party in any proceeding herein must file a motion to intervene in accordance with the Commission's rules.

A person obtaining intervenor 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 every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the

Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Vector to appear or to be represented at the hearing.

**David P. Boergers,**  
*Secretary.*

[FR Doc. 99-27358 Filed 10-19-99; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. EC00-2-000, et al.]

#### Louisville Gas and Electric Company, et al.; Electric Rate and Corporate Regulation Filings

October 12, 1999.

Take notice that the following filings have been made with the Commission:

#### 1. Louisville Gas and Electric Company, Kentucky Utilities Company

[Docket No. EC00-2-000]

Take notice that on October 5, 1999, Louisville Gas and Electric Company (LG&E) and Kentucky Utilities Company (KU) tendered for filing, pursuant to Section 203 of the Federal Power Act, 16 U.S.C. 824(b) (1999), and Part 33 of the Commission's regulations, 18 CFR part 33, an Application for approval of the disposition of their joint interests in certain combustion turbine units and related transmission facilities through a sale/leaseback transaction with a foreign entity, and for the waiver of certain filing requirements under Part 33 of the Commission's regulations.

The application requests that the Commission (1) Approve the disposition of the jurisdictional facilities associated with Units No. 5 and 6 at KU's E. W. Brown generating station through a sale/leaseback transaction with a foreign entity. The proposed disposition would permit LG&E and KU to share in certain tax benefits available to the foreign entity under the laws of the foreign entity's sovereign, and (2) Grant the waiver of the requirements of 18 CFR 33.2(g) (statement of cost of facilities involved in the sale/leaseback), and 18 CFR 33.3 (required exhibits).

LG&E and KU requested expedited consideration of the application.

A copy of this filing was served upon the Kentucky Public Service Commission.

*Comment date:* November 4, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 2. PSI Energy, Inc.

[Docket No. EC00-3-000]

Take notice that on October 5, 1999, PSI Energy, Inc. (PSI) tendered for filing pursuant to Section 203 of the Federal Power Act, 16 U.S.C. 824b and Section 33.1(a)(1) of the Federal Energy Regulatory Commission's Regulations, 18 CFR 33.1(a)(1) its application for approval of the sale of 53 of its communications towers to an affiliated company, Cinergy Communications, Inc. (CCI).

PSI states that it has served copies of its application upon the Indiana Utility Regulatory Commission.

*Comment date:* November 4, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 3. Avista Corp.

[Docket No. ER99-3408-000]

Take notice that on August 2, 1999, Avista Corp., tendered for filing a clarification of the rates under an executed service agreement with Cogentrix Energy Power Marketing, Inc., for Dynamic Capacity and Energy Service at cost-based rates under Avista Corp.'s FERC Electric Tariff, Original Volume No. 10. The service agreement was filed with the Commission on June 29, 1999.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 4. Allegheny Power Service Corporation; On behalf of Monongahela Power Company; The Potomac Edison Company; and West Penn Power Company; and (Allegheny Power)

[Docket No. ER99-4021-000]

Take notice that on October 5, 1999, Allegheny Power, on behalf of

Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company, tendered for filing an amendment to their application in Docket No. ER99-4021-000 requesting authorization for the Allegheny Power operating companies to sell power to one another at a market-based index price.

Allegheny Power requests an effective date one day after filing.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 5. Southern Company Energy Marketing L.P.

[Docket No. ER00-46-000]

Take notice that on October 5, 1999, Southern Company Energy Marketing L.P. (SCEM), tendered for filing an application requesting approval of its revised Market Rate Tariff (Revised Tariff), waiver of certain regulations and certain of the Federal Energy Regulatory Commission's filing requirements. The Revised Tariff permits SCEM to engage in sales of ancillary services at market-based rates to eligible customers in three discrete geographic markets within the United States.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 6. Tampa Electric Company

[Docket No. ER00-45-000]

Take notice that on October 5, 1999, Tampa Electric Company (Tampa Electric), tendered for filing a service agreement with Sonat Power Marketing L.P. (Sonat), under Tampa Electric's market-based sales tariff.

Tampa Electric proposes that the service agreement be made effective on September 17, 1999.

Copies of the filing have been served on Sonat and the Florida Public Service Commission.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 7. Tampa Electric Company

[Docket No. ER00-44-000]

Take notice that on October 5, 1999, Tampa Electric Company (Tampa Electric), tendered for filing a service agreement with the Reedy Creek

Improvement District (RCID) under Tampa Electric's market-based sales tariff.

Tampa Electric proposes that the service agreement be made effective on September 18, 1999.

Copies of the filing have been served on RCID and the Florida Public Service Commission.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 8. Western Systems Power Pool

[Docket No. ER00-43-000]

Take notice that on October 5, 1999, Deseret Generation & Transmission Cooperative, Inc. (Deseret), tendered for filing an executed Confirmation Agreement between Deseret and Arizona Public Service Company (APS) regarding a long-term purchase and sale transaction under the Western Systems Power Pool Agreement.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 9. Entergy Services, Inc.

[Docket No. ER00-42-000]

Take notice that on October 5, 1999, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Gulf States, Inc. (Entergy Gulf States), tendered for filing an Interconnection and Operating Agreement between Entergy Gulf States and RS Cogen, L.L.C.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 10. Entergy Services, Inc.

[Docket No. ER00-41-000]

Take notice that on October 5, 1999, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Gulf States, Inc. (Entergy Gulf States), tendered for filing a Letter Amendment to the Interconnection and Operating Agreement between Entergy Gulf States and RS Cogen, L.L.C.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

## 11. Entergy Services, Inc.

[Docket No. ER00-40-000]

Take notice that on October 5, 1999, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Gulf States, Inc. (Entergy Gulf States), tendered for filing a Letter Amendment to the Interconnection and Operating Agreement between Entergy Gulf States and RS Cogen, L.L.C.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**12. Broad River Energy LLC**

[Docket No. ER00-39-000]

Take notice that on October 5, 1999, Broad River Energy LLC (Broad River), tendered for filing information related to its market-based rate application also filed on this date. This information consists of an organizational chart listing all the entities affiliated with Broad River and its direct and upstream owners. Broad River requested confidential treatment of the organizational chart pursuant to 18 CFR 388.112.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**13. Broad River Energy LLC**

[Docket No. ER00-38-000]

Take notice that on October 5, 1999, Broad River Energy LLC (Broad River), tendered for filing an application for waivers and blanket approvals under various regulations of the Commission and for an order accepting its FERC Electric Rate Schedule No. 1. Additionally, Broad River has tendered for filing a power purchase agreement (PPA) between it and Carolina Power & Light Company. Broad River proposes that its Rate Schedule No. 1 and its sales under the PPA become effective upon commencement of service of the Broad River Energy Center (the Facility), a generation project currently being developed by Broad River in the State of South Carolina. The Facility will not be commercially operable until June, 2000.

Broad River intends to sell energy and capacity from the Facility pursuant to the terms of the PPA and other agreements at market-based rates, and on such terms and conditions to be mutually agreed to with the purchasing party.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**14. Portland General Electric Company**

[Docket No. ER00-36-000]

Take notice that on October 5, 1999, Portland General Electric Company (PGE), tendered for filing under PGE's Market-Based Rate Tariff, FERC Electric Tariff, First Revised Volume No. 11 (Docket No. ER99-1263-000), an executed Service Agreement for Service at Market-Based Rates with Mico, Inc.

Pursuant to 18 CFR Section 35.11, and the Commission's Order in Docket No. PL93-2-002 issued July 30, 1993, PGE respectfully requests that the Commission grant a waiver of the notice requirements of 18 CFR Section 35.3 to

allow the Service Agreement to become effective September 15, 1999.

A copy of this filing was caused to be served upon Mico, Inc., as noted in the filing letter.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**15. Portland General Electric Company**

[Docket No. ER00-35-000]

Take notice that on October 5, 1999, Portland General Electric Company (PGE), tendered for filing under PGE's FERC Electric Tariff, Original Volume No. 12 (Docket No. ER99-1224-000), an executed Service Agreement for the Sale, Assignment, or Transfer of Transmission Rights with Enron Power Marketing, Inc.

Pursuant to 18 CFR 35.11, and the Commission's Order in Docket No. PL93-2-002 issued July 30, 1993, PGE respectfully requests that the Commission grant a waiver of the notice requirements of 18 CFR 35.3 to allow the Service Agreement to become effective October 1, 1999.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**16. Southern California Edison Company**

[Docket No. ER00-34-000]

Take notice that on October 5, 1999, Southern California Edison Company (SCE), tendered for filing a revised Exhibit A to the Specifications for Wholesale Distribution Service to the Service Agreement for Wholesale Distribution Service between SCE-QF Resources Department and SCE Transmission and Distribution Business Unit under the Wholesale Distribution Access Tariff.

Copies of this filing were served upon the Public Utilities Commission of the State of California and all interested parties.

*Comment date:* October 25, 1999, in accordance with Standard Paragraph E at the end of this notice.

**Standard Paragraphs**

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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 motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at <http://www.ferc.fed.us/online/rims.htm> (call 202-208-2222 for assistance).

**David P. Boergers**

Secretary.

[FR Doc. 99-27356 Filed 10-19-99; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket Nos. CP99-61-000; CP99-62-000; CP99-63-000; and CP99-64-000]

**TriState Pipeline, L.L.C.; Notice to Postpone the Public Meetings for the Proposed Tristate Pipeline Project**

October 14, 1999.

By letter dated October 12, 1999, TriState Pipeline, L.L.C. (TriState) requested that the Commission hold in abeyance its application until TriState files a project status report no later than January 15, 2000. Therefore, the staff is postponing the TriState Pipeline Project Draft Environmental Impact statement (DEIS) public meetings scheduled for October 20 and 21, 1999. The written comment period on the DEIS is extended until January 15, 2000, and the staff may reschedule the public meetings following their review of TriState's project report.

**David P. Boergers,**

Secretary.

[FR Doc. 99-27357 Filed 10-19-99; 8:45 am]

BILLING CODE 6717-01-M

**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-6460-6]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request, Standards of Performance of Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI), Air Oxidation Unit Processes; and Distillation Operations**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C.

3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Standards of Performance of Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI), Air Oxidation Unit Processes; and Distillation Operations OMB Control Number 2060-0197, expiration date 12/31/99. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before November 19, 1999.

**FOR FURTHER INFORMATION CONTACT:** Sandy Farmer at EPA by phone at (202) 260-2740, by E-Mail at Farmer.Sandy@epamail.epa.gov or download a copy of the ICR off the Internet at <http://www.epa.gov/icr> and refer to EPA ICR No. 0998.06.

**SUPPLEMENTARY INFORMATION:**

**Title:** Standards of Performance of Volatile Organic Compound (VOC) Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI), Air Oxidation Unit Processes, Subpart III, and Distillation Operations, Subpart NNN; OMB Control No. 2060-0197; EPA ICR No. 0998.06, expiration 12/31/99. This is a request for an extension of a currently approved collection.

**Abstract:** This ICR contains recordkeeping and reporting requirements that are mandatory for compliance with 40 CFR 60.610, subpart III, Standards of Performance for VOC Emissions from SOCMI Air Oxidation Unit Processes and 40 CFR 60.660, subpart NNN, Standards of Performance for VOC from SOCMI Distillation Operations. This information is used by the Agency to identify sources subject to the standards and to insure that the best demonstrated technology is being properly applied. The standards require periodic recordkeeping to document process information relating to the sources' ability to meet the requirements of the standard and to note the operation conditions under which compliance was achieved.

In the Administrator's judgment, VOC emissions from SOCMI air oxidation unit processes and distillation operations cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Therefore, this source category. Owners or operators of the affected facilities described must make the

following one-time-only reports: notification of the date of construction or reconstruction; notification of the anticipated and actual dates of startup; notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; notification of the date of the initial performance test; and the results of the initial performance test. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports and records are required, in general, of all sources subject to NSPS.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on 06/04/99 (64 FR 30011); no comments were received.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 50 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

**Respondents/Affected Entities:** Owners/Operators of the Synthetic Organic Chemical Manufacturing Industry

**Estimated No. of Respondents:** 2,767  
**Frequency of Response:** Semiannual  
**Estimated Total Annual Hour Burden:** 278,687 hours.

**Estimated Total Annualized Capital, O&M Cost Burden:**

Send comments on the Agency's need for this information, the accuracy of the

provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 0998.06 and OMB Control No. 2060-0197 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Office of Policy, Regulatory Information Division (2137), 401 M Street, SW., Washington, DC 20460; and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

Dated: October 13, 1999.

**Joseph Retzer,**

*Director, Regulatory Information Division.*

[FR Doc. 99-27390 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[Docket No. A-99-31; FRL-6459-3]

### List of Source Categories

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of receipt of a complete petition.

**SUMMARY:** This notice announces that EPA has created a two-piece beer and beverage can coating (two-piece can) subcategory within the Metal Can (Surface Coating) source category. This notice also announces the receipt of a complete petition from the Can Manufacturers' Institute (CMI) requesting EPA to remove the two-piece can subcategory from the List of Source Categories (Source Category List). The Source Category List was developed pursuant to section 112(c)(1) of the Amendments to the 1990 Clean Air Act (Act) and published in the **Federal Register** on July 16, 1992 (57 FR 31576).

We have determined that the original petition submittal by CMI, dated November 4, 1996, plus the supplemental materials provided by CMI through April 21, 1999, will support an assessment of the human health impacts associated with hazardous air pollutant (HAP) emissions from two-piece can coating operations. In addition, the data submitted by CMI will support an assessment of the environmental impacts associated with HAP emissions from the two-piece can coating subcategory. Consequently, we have concluded that CMI's petition is complete as of April 21, 1999, the date

of the last supplement, and is ready for public comment and the technical review phase of our delist petition evaluation process.

This notice invites the public to provide additional information, beyond that filed in the petition, on sources, emissions, exposure, health effects and environmental impacts associated with HAP emissions from two-piece can coating operations that may be relevant to our technical review.

**DATES:** Comments and additional data will be accepted if received on or before November 19, 1999.

**ADDRESSES:** *Documents.* A copy of the complete petition is contained in a docket available at the Air and Radiation Docket and Information Office, 401 M Street SW, Room M-1500 (6102), Waterside Mall, Washington, DC 20460. The docket number for this action is A-99-31. You may inspect the petition and copy it for offsite review between 8:30 a.m. and 5:30 p.m. EST, Monday through Friday. A reasonable fee may be charged for copying.

*Comments and Data Submissions.* Comments and additional data should be submitted (in duplicate if possible) to: The Docket Clerk, Air and Radiation Docket and Information Office, 401 M Street SW, Room M-1500 (Mail Code 6102), Waterside Mall, Washington, DC 20460.

**FOR FURTHER INFORMATION CONTACT:** Kelly Rimer, Emission Standards Division (MD-13), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone (919) 541-2962, electronic mail address: rimer.kelly@epa.gov.

## I. Introduction

### A. What Are Hazardous Air Pollutants?

Hazardous air pollutants include a wide variety of organic and inorganic substances released from large and small industrial operations, fossil fuel combustion, gasoline and diesel-powered vehicles, and many other sources. The HAPs have been associated with a wide variety of adverse health effects, including cancer, neurological effects, reproductive effects, and developmental effects. The health effects associated with the various HAPs may differ depending upon the toxicity of the individual HAP and the particular circumstances of exposure, such as the amount of chemical present, the length of time a person is exposed, and the stage in life of the person when the exposure occurs. The list of HAPs can be found in section 112(b)(1) of the Act. The HAPs list provides the basis for research, regulation, and other related

EPA activities under section 112 of the Act.

### B. What Is the Source Category List?

Section 112(c) of the Act requires the EPA to publish a list of all categories and subcategories of major and area sources of HAPs which will be subject to regulation. A "major source" is any stationary source (including all emission points and units located within a contiguous area and under common control) of air pollution that has the potential to emit, considering controls, 10 tons or more per year of any HAP, or 25 or more tons per year of any combinations of HAPs. An "area source" is a stationary source that emits HAPs in amounts less than 10 or 25 tons per year. For an area source category to be listed, the EPA must determine that the source category presents a threat to human health or to the environment. Under section 112(d), the Act requires EPA to establish national emission standards for source categories based on maximum achievable control technology (MACT) for major source categories and to set either MACT or generally available control technology (GACT) standards for area source categories.

The EPA published the initial Source Category List in the **Federal Register** on July 16, 1992 (57 FR 31576); you can find the most recent update to the Source Category List in the February 12, 1998 **Federal Register** (63 FR 7155).

### C. What Is a Source Category Delist Petition?

A source category delist petition is a formal request to the EPA from an individual or group to remove a specific source category from the Source Category List. The removal of a source category from the list eliminates it from consideration in EPA's program to promulgate MACT standards.

Any group or person may petition the EPA to delete a source category from the Source Category List. The Administrator must grant or deny a petition within 12 months of receiving a complete petition.

Section 112(c)(9)(B) provides that the Administrator may delete a source category from the Source Category List if she determines that no source in the category:

1. Emits carcinogens in amounts that may result in a lifetime risk of cancer exceeding one in a million to the individual most exposed;
2. Emits noncarcinogens in amounts that exceed an ample margin of safety to protect the public health; and
3. Emits HAPs in amounts that will result in adverse environmental effects.

The EPA will not grant a petition to delete a source category or subcategory from the Source Category List pursuant to section 112(c)(9)(B) unless EPA makes an initial determination that each of the statutory criteria appear to be met for each HAP emitted by each individual source within the category or subcategory.

### D. What Is a Subcategory?

A subcategory is a group of similar sources within a given source category. As part of the regulatory development process, EPA evaluates the similarities and differences between industry segments or groups of facilities comprising a source category. Different source categories may be evaluated and subcategorized in different ways.

In establishing subcategories, EPA considers factors such as process operations (type of process, raw materials, chemistry/formulation data, associated equipment, and final products); emission characteristics (amount and type of HAP); control device applicability; and opportunities for pollution prevention. The EPA may also look at existing regulations or guidance from States and other regulatory agencies in determining subcategories.

The Act does not expressly establish a process for deletion of a subcategory from the Source Category List. However, EPA construes the Act to permit petitions to delete a specified subcategory in those instances where EPA has previously created such a subcategory within the applicable source category.

### E. How Does EPA Review a Petition To Delist a Source Category or Subcategory?

The petition review process proceeds in two phases: a completeness determination and a technical review. During the completeness determination, we conduct a broad review of the petition to determine whether or not all the necessary subject areas are addressed and whether reasonable information and analyses are presented for each of these subject areas. Once the petition is determined to be complete, we place a notice of receipt of a complete petition in the **Federal Register** and commence the technical review phase of our decision-making process.

That **Federal Register** notice announcing receipt of a complete petition also announces a public comment period on the petition. The technical review involves a more thorough scientific review of the petition to determine whether the data,



analyses, interpretations, and conclusions in the petition are appropriate and technically sound. The technical review will also determine whether or not the petition appears to satisfy the necessary requirements of section 112(c)(9)(B) and to provide adequate support for a decision to delist the source category or subcategory. All comments and data submitted during the public comment period are considered during the technical review.

The Agency considers the following information relevant to the evaluation of any petition:

1. Identification of sources included in the source category;
2. Estimation of emissions from identified sources;
3. Estimation of ambient levels, either modeled or measured, of the emitted HAPs;
4. Assessment of the toxicity of chemicals being released; and
5. Evaluation of the impact to humans, plants, and animals from such emissions (e.g., cancer, noncancer effects, ecological effects).

#### *F. How Is the Decision To Delist a Source Category or Sub-Category Made?*

The decision to either grant or deny a petition to delist a category or subcategory is made after a comprehensive technical review of both the petition and the information received from the public to determine whether the petition appears to satisfy the requirements of section 112(c)(9)(B) of the Act.

The EPA may modify the Source Category List without rulemaking in instances where we conclude that a category or subcategory did not originally meet or no longer meets the quantitative emission criteria for inclusion on the list. However, in instances where we delete a category or subcategory based on the risk criteria set forth in section 112(c)(9)(B), we have determined that it is appropriate to utilize rulemaking procedures. Thus, if the Administrator decides to grant a petition to delist a category or subcategory under this provision, EPA will publish a notice of proposed rulemaking in the **Federal Register**. That notice will propose to remove the source category or subcategory from the Source Category List and present the reasoning for doing so.

However, if the Administrator decides to deny a petition under section 112(c)(9)(B), an explanation of the reasons for denial will be published instead. A notice of denial constitutes final Agency action of nationwide scope and applicability and is subject to

judicial review as provided in section 307(b) of the Act.

## **II. Decision To Subcategorize**

On November 4, 1996, we received a request from CMI to create a two-piece beer and beverage can subcategory within the Metal Can (Surface Coating) source category. We reviewed the request to subcategorize and conducted our own analysis of existing metal can manufacturing and surface coating operations. Based on the information presented by CMI and on our analysis of the source category, we determined that designating two-piece beer and beverage cans as a subcategory was appropriate under the authority described below and for the following reasons.

In general, we make the decision to establish subcategories within a source category as part of the process of developing a MACT standard applicable to that category. In establishing subcategories, we typically consider factors such as process operations, emission characteristics, control device applicability, and opportunities for pollution prevention. For the two-piece aluminum beer and beverage can subcategory of the metal can industry, the distinction is based primarily on differences in the process operations (e.g., types of coatings, inks and solvents used); associated process equipment; and process configurations (e.g., overall process line size and facility layout).

A two-piece beer and beverage can subcategory is consistent with existing new source performance standards and control technology guideline approaches. Subpart WW of 40 CFR part 63 addresses volatile organic compound emissions (many of which are also listed as HAP) and is specifically titled: "Standards of Performance for the Beverage Can Surface Coating Industry" and defines beverage can as "any two-piece steel or aluminum container in which soft drinks or beer, including malt liquor, are packaged" and two-piece can as "any beverage can that consists of a body manufactured from a single piece of steel and aluminum."

Metal can surface coating operations are differentiated by the type of product(s) stored inside the can which determine the types of coatings applied to the interior/exterior surfaces of the can. The manufacturing and coating processes equipment configuration within the metal can industry segments are different in terms of configuration, size, and complexity than other types of can manufacturing. None of the 61 two-piece beverage can facilities located in the U.S. produce other types of cans. There are six facilities that have an

"ends" (e.g., can tops with push/pull tab) line as part of the on-site manufacturing operations, and there are three "ends" only facilities that produce ends for two-piece beer and beverage cans. Can "ends" are not included in this subcategory and will be addressed separately.

Our analysis of existing metal can manufacturing and surface coating operations resulted in the decision to establish a subcategory for two-piece aluminum beer and beverage cans. This subcategory includes all coating; cleaning; and associated (i.e., storage, mixing, transfer, handling, surface preparation (can washers), and wastewater) operations related to can bodies, except ends.

As provided by section 112(e)(4), our decision to create the specified subcategory is not a final Agency action and as such is not reviewable at this time. The decision to create the specified subcategory will be final and subject to review only at such time as we decide to delete the subcategory or when we promulgate a MACT standard applicable to the subcategory. In the event that we decide to deny the present petition to delist this subcategory, we may reconsider our decision on subcategorization during subsequent development of a MACT standard for the Metal Can (surface coating) category.

## **III. Completeness Determination and Request for Public Comment**

On November 4, 1996, the CMI submitted a petition to remove the two-piece can subcategory from the Source Category List. The EPA reviewed the initial petition to delete the subcategory and determined that additional information was needed on several of the HAPs emitted by this subcategory in order for the petition to be complete. The petitioner submitted additional documents from 1997 through April 1999 to address the information gaps.

After reviewing all of the supplemental information, we determined that the essential subject areas had been addressed, and that the petition is complete and ready for technical review. The EPA has therefore determined that the petition was complete as of the date of the last supplemental submission on April 21, 1999. The EPA must act to grant or deny this petition within 12 months from that date. The EPA has begun its comprehensive technical review of the CMI petition. We invite interested members of the public to submit any additional information which may be relevant to our analysis of whether the statutory criteria for delisting are met.



**IV. Description of the Petition**

The complete petition provided by CMI contains the following information:

A. Identification of 16 HAPs emitted from the two-piece can subcategory

(Table 1). The petition provides more detailed information and analysis on ethylene glycol butyl ether (EGBE) and formaldehyde than on the other HAPs. The petitioner provides more data on

EGBE due to the fact that it is the HAP emitted in highest quantities, and more on formaldehyde because it is a probable human carcinogen emitted in moderate quantities.

TABLE 1.—IDENTIFICATION OF HAPs

HAP	Chemical abstract service registry No. (CASRN)
Ethylene glycol monobutyl ether (EGBE) .....	111-76-2
Formaldehyde .....	50-00-0
Diethylene glycol butyl ether (DGBE) .....	112-34-5
Diethylene glycol ethyl ether (DGEE) .....	111-90-0
Diethylene glycol hexyl ether (DGHE) .....	112-59-4
Ethylene glycol hexyl ether (EGHE) .....	112-25-4
Benzene .....	71-43-2
Ethyl benzene .....	100-41-4
Ethylene oxide .....	75-21-8
Hydrogen fluoride .....	7664-39-3
Methanol .....	67-56-1
Methyl isobutyl ketone .....	108-10-1
Propylene oxide .....	75-56-9
Styrene .....	100-42-5
Toluene .....	108-88-3
Xylenes .....	1330-20-7

B. For each HAP, the petitioner provides summaries of and references for qualitative and quantitative human health effects information based on data from EPA, the State of California and from industry. For EGBE and formaldehyde, CMI presents analyses of human health effects studies.

C. The petition includes emissions estimates for all HAPs listed in Table 1 and identifies the route of exposure of potential concern as being air. To assess maximum off-site air concentrations of HAPs, CMI uses a tiered modeling approach described in a 1992 EPA document, "A Tiered Approach for Assessing Risks due to Emissions of Hazardous Air Pollutants" (EPA-450/4-92-001). Tiered modeling involves the use of successive modeling techniques to move from conservative "worst case" estimates of the ambient concentrations of a substance emitted from a source toward more realistic site specific estimates of the ambient concentrations.

D. For all identified HAPs, the petitioner provides numerical estimates of risks to humans.

E. The CMI's ecological assessment addresses whether HAP emissions are likely to result in adverse environmental effects. The analysis and discussion consider emission levels, atmospheric fate, biodegradation and bioconcentration, and conclude that all HAP emissions from this subcategory are unlikely to have an adverse effect on aquatic biota, terrestrial wildlife, or other natural resources. To support this

position, the petitioner uses as its principle source of information the EPA's Hazardous Substances Database. For EGBE, CMI provides additional information; an ecological analysis for EGBE which was also submitted to the Agency under the petition to remove EGBE from the HAP list. The petitioner combines that analysis with a discussion of potential adverse impacts of EGBE from two-piece can operations and finds that adverse environmental effects are unlikely to occur as a result of EGBE emissions from the subcategory.

F. The petition includes an uncertainty analysis which considers emissions projections, emissions modeling, exposure analysis, mixtures and co-location of facilities.

The petition states that the data and parameters employed in each step of risk assessment embody some degree of uncertainty that could affect the conclusions drawn. The petitioner has attempted to reduce the likelihood of underestimation by using upper bound estimates, parameters and assumptions which result in maximum exposure estimates that do not exceed a health-based exposure limit for any emitted HAP. To further reduce the likelihood of underestimating risks, the petition considers additivity by summing the potential impacts of all of the emitted noncarcinogens and by summing potential impacts of all emitted carcinogens.

Dated: October 8, 1999.

**Robert Perciasepe,**

*Assistant Administrator for Air and Radiation.*

[FR Doc. 99-27142 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6460-8]

### Adequacy Status of Lake and Porter Counties, Indiana Submitted Ozone Attainment Demonstration for Transportation Conformity Purposes

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of inadequacy.

**SUMMARY:** In this document, EPA is notifying the public that EPA has found that the Lake and Porter Counties, Indiana ozone attainment demonstration does not contain adequate mobile source emission budgets. On March 2, 1999, the D.C. Circuit Court ruled that submitted State Implementation Plans (SIPs) cannot be used for conformity determinations until EPA has affirmatively found them adequate. Since the April 30, 1998, submittal does not contain adequate budgets, this attainment demonstration can not be used for future conformity determinations.

**FOR FURTHER INFORMATION CONTACT:** The finding and the response to comments

will be available at EPA's conformity website:

<http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Ryan Bahr, environmental engineer, Regulation Development Section (AR-18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-4366, bahr.ryan@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### Background

Throughout this document, whenever "we", "us" or "our" is used, we mean EPA. Today's notice is simply an announcement of a finding that we have already made. EPA Region 5 sent a letter to the Indiana Department of Environmental Management on September 28, 1999, stating that the Lake and Porter Counties submitted ozone attainment demonstration does not contain adequate mobile source emission budgets. This finding will also be announced on EPA's conformity website: <http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review, and it also should not be used to prejudge EPA's ultimate approval of the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

We've described our process for determining the adequacy of submitted SIP budgets in guidance (May 14, 1999 memorandum titled "Conformity Guidance on Implementation of March 2, 1999 Conformity Court Decision"). We followed this guidance in making our adequacy determination.

**Authority:** 42 U.S.C. 7401-7671 q.

Dated: October 7, 1999.

**David A. Ullrich,**

*Acting Regional Administrator, Region 5.*

[FR Doc. 99-27387 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6460-7]

### Adequacy Status of Milwaukee, WI Submitted Ozone Attainment Demonstration for Transportation Conformity Purposes

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Inadequacy.

**SUMMARY:** In this document, EPA is notifying the public that EPA has found that the Milwaukee, Wisconsin ozone attainment demonstration does not contain adequate mobile source emission budgets. On March 2, 1999, the DC Circuit Court ruled that submitted State Implementation Plans (SIPs) cannot be used for conformity determinations until EPA has affirmatively found them adequate. Since the April 30, 1998, submittal does not contain adequate budgets, this attainment demonstration can not be used for future conformity determinations.

**FOR FURTHER INFORMATION CONTACT:** The finding and the response to comments will be available at EPA's conformity website: <http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Michael G. Leslie, Regulation Development Section (AR-18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604, (312) 353-6680, leslie.michael@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### Background:

Throughout this document, whenever "we", "us" or "our" is used, we mean EPA. Today's notice is simply an announcement of a finding that we have already made. EPA Region 5 sent a letter to the Wisconsin Department of Natural Resources on September 28, 1999, stating that the Milwaukee, Wisconsin submitted ozone attainment demonstration does not contain adequate mobile source emission budgets. This finding will also be announced on EPA's conformity website:

<http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review, and it also should not be used to prejudge EPA's ultimate approval of the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

We've described our process for determining the adequacy of submitted SIP budgets in guidance (May 14, 1999 memorandum titled "Conformity Guidance on Implementation of March 2, 1999 Conformity Court Decision"). We followed this guidance in making our adequacy determination.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: October 7, 1999.

**David A. Ullrich,**

*Acting Regional Administrator, Region 5.*

[FR Doc. 99-27388 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6460-9]

### Adequacy Status of Chicago, IL Submitted Ozone Attainment Demonstration for Transportation Conformity Purposes

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Inadequacy.

**SUMMARY:** In this document, EPA is notifying the public that EPA has found that the Chicago, Illinois ozone attainment demonstration does not contain adequate mobile source emission budgets. On March 2, 1999, the D.C. Circuit Court ruled that submitted State Implementation Plans (SIPs) cannot be used for conformity

determinations until EPA has affirmatively found them adequate. Since the April 30, 1998, submittal does not contain adequate budgets, this attainment demonstration can not be used for future conformity determinations.

**FOR FURTHER INFORMATION CONTACT:** The finding and the response to comments will be available at EPA's conformity website: <http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Patricia Morris, Environmental Scientist, Regulation Development Section (AR-18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8656, [morris.patricia@epa.gov](mailto:morris.patricia@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**Background:** Throughout this document, whenever "we", "us" or "our" is used, we mean EPA. Today's notice is simply an announcement of a finding that we have already made. EPA Region 5 sent a letter to the Illinois Environmental Protection Agency on September 28, 1999, stating that the Chicago, Illinois submitted ozone attainment demonstration does not contain adequate mobile source emission budgets. This finding will also be announced on EPA's conformity website: <http://www.epa.gov/oms/traq>, (once there, click on the "Conformity" button, then look for "Adequacy Review of SIP Submissions for Conformity").

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review, and it also should not be used to prejudge EPA's ultimate approval of the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

We've described our process for determining the adequacy of submitted

SIP budgets in guidance (May 14, 1999 memorandum titled "Conformity Guidance on Implementation of March 2, 1999 Conformity Court Decision"). We followed this guidance in making our adequacy determination.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: October 7, 1999

**David A. Ullrich,**

*Acting Regional Administrator, Region 5.*

[FR Doc. 99-27389 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-6461-1]

**The National Advisory Council for Environmental Policy and Technology (NACEPT); New Standing Committee on Sectors**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notification of Public Advisory NACEPT Standing Committee on Sectors Workgroup meeting; open meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Standing Committee on Sectors workgroup will meet on the date and time described below. The meeting is open to the public. Seating at the meeting will be a first-come basis and limited time will be provided for public comment. For further information concerning this meeting, please contact the individual listed with the announcement below.

Petroleum Refining Sector Workgroup Meeting—November 3-4, 1999.

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the National Advisory Council for Environmental Policy and Technology (NACEPT) Petroleum Refining Sector Workgroup on November 3 and 4, 1999. A Concurrent project team meeting will be held from 9:00 am until 4:30 pm CDT on Wednesday, November 3, 1999. The full workgroup will meet from 8:30 am until 4:30 pm CDT on Thursday, November 4, 1999. The meeting will be held at the Holiday Inn Hotel Downtown—Superdome, 330 Loyola Avenue, New Orleans, Louisiana. The hotel telephone number is 504-581-1600.

The workgroup meeting agenda includes an update on the status of the Accidental Release Information Communication Project, Refinery Air Information Reporting System Project,

and the Equipment Leaks Project. The workgroup also plans to discuss compliance goals for the petroleum refining industry and regulatory options for potential alternate leak detection and repair work practice protocols. A public comment period has been scheduled from approximately 1:00 pm until 2:00 pm CDT on Thursday, November 4, 1999.

**SUPPLEMENTARY INFORMATION:** NACEPT is a federal advisory committee under the Federal Advisory Committee Act, Public Law 92463. NACEPT provides advice and recommendations to the Administrator and other EPA officials on a broad range of domestic and international environmental policy issues. NACEPT consists of a representative cross-section of EPA's partners and principle constituents who provide advice and recommendations on policy issues and serve as a sounding board for new strategies that the Agency is developing.

In follow-up to completion of work by EPA's Common Sense Initiative (CSI) Council, the Administrator has asked NACEPT to create a new Standing Committee on Sectors. This will provide a continuing Federal Advisory Committee forum from which the Agency can continue to receive valuable multi-stakeholder advice and recommendations on sector approaches.

Based on the lessons learned in CSI and many other sector based programs, the Agency has developed a Sector Based Environmental Protection Action Plan to reinforce and expand sector based approaches to achieving environmental results. The Standing Committee on Sectors will, through NACEPT (the Council): (1) Continue to support the on-going CSI work, (2) support the implementation of the Action Plan, as noted above, and (3) serve as a vehicle to get stakeholder reaction and input on sector based issues in a timely way.

For further information concerning this meeting of the Petroleum Refining Sector workgroup, please contact either Craig Weeks, Designated Federal Officer (DFO), at US EPA Region 6 (6EN), 1445 Ross Avenue, Dallas, TX 75202-2733, by telephone at 214-665-7505 or E-mail at [weeks.craig@epa.gov](mailto:weeks.craig@epa.gov) or Steve Souders, Alternate DFO, at US EPA (5306W), 401 M Street, SW, Washington, DC 20460, by telephone at 703-308-8431 or E-mail at [souders.steve@epa.gov](mailto:souders.steve@epa.gov).

Inspection of Subcommittee Documents: Documents relating to the above topics will be publicly available at the meeting. Thereafter, Key documents and the minutes of the

meeting will be available electronically on the web site, or by calling the DFO. NACEPT Standing Committee on Sectors Subcommittee information can be accessed electronically on our web site at <http://www.epa.gov/sectors>.

Dated: October 4, 1999.

**Gregory Ondich,**

*Acting Designated Federal Officer.*

[FR Doc. 99-27386 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

OPP-30483; FRL-6387-5

### Pesticide Products; Registration Application

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of an application to register a pesticide product containing a new active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**DATES:** Written comments, identified by the docket control number OPP-30483, must be received on or before November 19, 1999.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA. It is imperative that you identify docket control number OPP-30483 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703 305-6502; and e-mail address: [sibold.ann@epa.gov](mailto:sibold.ann@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	112 311 32532	Animal production Food manufacturing Pesticide manufac-turing

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

###### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-30483. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy.,

Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

###### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-30483 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-30483. Electronic comments may also be filed online at many Federal Depository Libraries.

###### D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the "FOR FURTHER INFORMATION CONTACT."

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Registration Application

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

*File Symbol:* 241-GOT. *Applicant:* American Cyanamid Company, Agricultural Research Division, P.O. Box 400 Princeton, NJ 08543 00. *Product Name:* Chlorfenapyr Insecticide Cattle Ear Tags. *Active Ingredient:* 4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile at 30%. *Proposed classification/Use:* For use to control horn flies and lice on cattle.

**Authority:** 7 U.S.C. 136.

### List of Subjects

Environmental protection, Pesticides and pest.

Dated: October 8, 1999.

**Richard P. Keigwin, Jr.,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 99-27396 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-30482; FRL-6382-8]

### Pesticide Products; Registration Applications

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**DATES:** Written comments, identified by the docket control number OPP-30482, must be received on or before November 19, 1999.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-30482 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** The Product Managers, Registration Division (7505C), listed in the table below:

Product Managers	Office location/telephone	Address
Dani Daniel	Rm. 211, CM #2, 703-305-5409, e-mail: daniels.dani@epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Dennis McNeilly	Rm. 213, CM #2, 703-308-6742, e-mail: mcneilly.dennis@epa.gov.	Do.
Susan Stanton	Rm. 239, CM #2, 703-305-5218, e-mail: stanton.susan@epa.gov.	Do.
Mary Waller (PM-21)	Rm. 249, CM #2, 703-305-9354, e-mail: waller.mary@epa.gov.	Do.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

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

Cat-egories	NAICS codes	Samples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number

OPP-30482. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-30482 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control

number OPP-30482. Electronic comments may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under "FOR FURTHER INFORMATION CONTACT."

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. Registration Applications**

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these

applications does not imply a decision by the Agency on the applications.

#### *Products Containing Active Ingredients not Included in any Previously Registered Products*

1. File Symbol: 38719-T. Applicant: BOC Gases America, 575 Mountain Ave., Murray Hill, NJ 771-1375. Product name: ECO<sub>2</sub> FUME Fumigant Gas. Insecticide. Active ingredient: Phosphine (PH<sub>3</sub>) at 2%. Proposed classification/Use: Restricted. For use against insects which infest nonfood commodities and structures. Type registration: Conditional.

2. File Symbol: 100-OLL. Applicant: Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. Product name: Flagship. Insecticide/Miticicide. Active ingredient: Thiamethoxam 4H-1,3,5-oxadiazin-4-imine, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro- at 25%. Proposed classification/Use: None. For foliar and systemic control of insect pests in greenhouses and ornamentals. Type registration: Conditional.

3. File Symbol: 3125-LGG. Applicant: Bayer Corporation, 8400 Hawthorne Rd., P.O. Box 4913, Kansas City, MO 64120. Product name: Flucarbazone-Sodium Technical Herbicide. Herbicide. Active ingredient: Flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole-1-carboxamide, sodium salt at 95.6%. Proposed classification/Use: None. For use only in the manufacturing of herbicides.

4. File Symbol: 3125-LGL. Applicant: Bayer Corporation. Product name: Flucarbazone-Sodium 70% Water Dispersible Granular Herbicide. Herbicide. Active ingredient: Flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole-1-carboxamide, sodium salt at 70%. Proposed classification/Use: None. For post emergence control of wild oat and green foxtail in all types of spring wheat.

5. File Symbol: 3125-LGU. Applicant: Bayer Corporation. Product name: Flucarbazone-Sodium 70% Water Dispersible Granular In Water Soluble Packets. Herbicide. Active ingredient: Flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole-1-carboxamide, sodium salt at 70%. Proposed classification/Use: None. For post emergence control of wild oat and green foxtail in all types of spring wheat.

6. File Symbol: 60063-RR. Applicant: Sipcam Agro USA, Inc., 70 Mansell Court, Suite 230, Roswell, GA 30076.

Product name: Tetraconazole Technical. Fungicide. Active ingredient: Tetraconazole: [1-[2, (2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4 triazole] at 97.0%. Proposed classification/Use: None. Tetraconazole Technical is intended for the formulation into end-use products for use on sugar beets, peanuts, and turf. Type registration: Conditional.

7. File Symbol: 60063-RE. Applicant: Sipcam Agro USA, Inc. Product name: Eminent 125SL Fungicide. Fungicide. Active ingredient: Tetraconazole: [1-[2, (2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4 triazole] at 11.6%. Proposed classification/Use: None. Eminent 125SL is intended for the control of Cercospora leaf spot and powdery mildew disease of sugar beets; early and late leaf spot, rust, web blotch, and southern blight of peanuts and dollar spot, copper spot, rust, Southern blight, brown patch, red thread, anthracnose, powdery mildew, etc. diseases of turf. Type registration: Conditional.

#### List of Subjects

Environmental protection, Pesticides and pest.

Dated: September 29, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99-27394 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-F

#### ENVIRONMENTAL PROTECTION AGENCY

[PF-895; FRL-6386-9]

#### Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-895, must be received on or before November 19, 1999.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

"SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-895 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Indira Gairola, Minor Use Inert's, & Emergency Response Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-6379; and e-mail address: gairola.indira@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

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

Cat-egories	NAICS	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register-Environmental Documents." You can also go directly to

the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-895. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-895 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by E-mail to: "[opp-docket@epa.gov](mailto:opp-docket@epa.gov)," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic



submissions will be accepted in Wordperfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number PF-895. Electronic comments may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the "FOR FURTHER INFORMATION CONTACT" section.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under

section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

### **List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 7, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

### **Monsanto Company**

*PP 1E4031*

EPA has received a pesticide petition (PP 1E4031) from Monsanto Company, 700 14th St., NW., (1100), Washington, DC 20005 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of 3-dichloroacetyl-5-(2-furanyl)-2,2-dimethylloxazolidine (furalazole in or on the raw agricultural commodity (RAC) field corn grain, forage, and fodder at < 0.01 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

### *A. Residue Chemistry*

1. *Plant metabolism.* The metabolism in corn was studied with radiolabeled furalazole in the green house and the field. Parent furalazole was not found in any of the corn samples. Furalazole is rapidly and extensively metabolized to a large number of highly polar metabolites characterized as weak organic acids or residues conjugated to natural sugars. No parent furalazole was found in the plants at all.

2. *Analytical method.* Monsanto has developed an analytical method using gas liquid chromatography with electron capture detection that has a verified limit of quantitation (LOQ) of 0.01 ppm for parent MON 13,900 in corn grain, forage, and fodder. This method has been validated by the Agency.

3. *Magnitude of residues.* Monsanto has conducted five residue field studies with furalazole applied pre-emergence to corn at rates up to 0.75 pound per acre. Analysis of corn forage, silage, fodder, and grain showed no residues with an analytical method that is validated at the lower limit of 0.01 ppm. Three residue field studies with furalazole applied pre-emergence to corn at exaggerated rates up to 26 times the proposed maximum use rate showed no measurable residues (< 0.01 ppm) in corn grain. Based on these results, it was concluded that the potential for measurable concentration of furalazole in processed commodities of corn was very low and that processing studies were not required.

### *B. Toxicological Profile*

1. *Acute toxicity*—i. An acute oral toxicity study in the rat with an LD<sub>50</sub> of 869 mg/kg. Toxicity Category III.

ii. An acute dermal toxicity study in the rabbit with an LD<sub>50</sub> of > 5,000 mg/kg. Toxicity Category IV.

iii. An acute inhalation study in the rat with a 4-hour inhalation LC<sub>50</sub> of 2.3 milligrams per liter (mg/L), the highest attainable concentration. Toxicity Category III.

iv. A rabbit eye irritation study in which furalazole is determined to be a mild eye irritant. Toxicity Category III.

v. A rabbit primary dermal irritation study indicating that furalazole is a negligible dermal irritant. Toxicity Category IV.

vi. A dermal sensitization study in guinea pigs indicating that furalazole does not produce delayed contact hypersensitivity.

2. *Genotoxicity.* Mutagenicity studies including *in vivo/in vitro* unscheduled DNA synthesis (UDS) in rat hepatocytes, gene mutation in cultured Chinese hamster ovary cells (CHO/HGPRT), and



*in vivo* micronucleus assay were negative. A *Salmonella typhimurium*/mammalian microsome mutagenicity assay, and without metabolic activation, indicated that furilazole induced a reproducible mutagenic response, but only at a high and precipitating dose.

3. *Reproductive and developmental toxicity*—i. A rat developmental effects study with a no observed adverse effect level (NOAEL) for maternal toxicity of 10 milligrams/kilograms/day (mg/kg/day) and developmental toxicity of 10 mg/kg/day.

ii. A 2-generation reproduction study in rats fed diets containing 0, 15, 150, and 1,500 ppm furilazole. The NOAEL for systemic toxicity was 150 ppm (9 to 11 mg/kg/day) for both parents and offspring. There were no treatment-related effects on reproductive performance or offspring survival at any dose level; therefore, the NOAEL for reproductive toxicity was 1,500 ppm or 101 mg/kg/day.

4. *Subchronic toxicity*—i. A 90-day oral toxicity study in the rat with a NOAEL of 100 ppm, or 7 mg/kg/day.

ii. A 90-day oral toxicity study in the dog with a NOAEL of 15 mg/kg/day.

iii. A 21-day repeated dose dermal toxicity study in rats with a NOAEL > 1,000 mg/kg/day.

5. *Chronic toxicity*. A 24-month chronic feeding and oncogenicity study in the rat at doses of 0, 5, 100, 1,000, and 2,000 (females)/2,500 (males) ppm. The liver, stomach, and testes were the main target organs. Oncogenic effects were seen in the stomach and liver of females and in the stomach, liver, and testes of males. The NOAEL for oncogenic effects was 100 ppm (5.05 mg/kg/day for males and 6.03 mg/kg/day for females). The NOAEL for chronic toxicity was 5 ppm (0.26 mg/kg/day for males) and 100 ppm (6.03 mg/kg/day for females). An 18-month oncogenicity study in mice fed doses of 0, 5, 40, 400, 1,250, and 2,500 (males)/3,500 (females) ppm. The liver and the lung were the target organs. Oncogenic effects were observed in livers and lungs of both sexes. The NOAEL for chronic toxicity and for oncogenic effects was 40 ppm (5.93 mg/kg/day in males) and 400 ppm (92.0 mg/kg/day in females).

6. *Animal metabolism*. Because field trial residue data showed non-detectable residues of furilazole in corn, neither animal metabolism nor residue transfer studies with livestock were required. It is considered likely that metabolism will be similar to that of other dichloroacetamide safeners in mammals which are characterized by extensive metabolism and elimination of most of the residue from the body with very low

levels of parent safener, if any, retained in the tissues. The major route of metabolism is typically glutathione conjugation followed by formation of an aldehyde intermediate which is then either oxidized to an oxamic acid or reduced to the corresponding alcohol.

7. *Metabolite toxicology*. The metabolism of furilazole is extensive and results in a large number of polar metabolites each of which is present in soil or corn plants in very low concentrations. These metabolites have not been identified as being of toxic concern.

Based on the available toxicity data, Monsanto believes the reference dose (RfD) for furilazole should be based on the NOAEL observed in the chronic rat study, 0.26 mg/kg/day for males or 6 mg/kg/day for females. Using an uncertainty factor of 100, the RfD would be 0.0026 mg/kg/day. For cancer risk assessment for furilazole, Monsanto believes that margin of exposure (MOE) assessment should be calculated using the oncogenic NOAEL of 5 mg/kg/day observed in the rat, which was the most sensitive species.

#### C. Aggregate Exposure

1. *Food*. Monsanto has used the Theoretical Maximum Residue Contribution (TMRC) as a conservative estimate of the potential dietary exposure for furilazole. This approach assumes that 100% of all RAC for which tolerances have been established for acetochlor, bear tolerance-level (0.01 ppm) residues of furilazole. This overestimate of actual dietary exposure provides a quite conservative basis for risk assessment.

i. *Drinking water*. Furilazole is photolyzed rapidly with half-lives of 8 hours in water in the presence of humic acid, and 8 to 9 days in soil. The aerobic soil half-life is approximately 5 to 8 weeks. Furilazole is stable to hydrolysis, but its metabolites that have modifications to the dichloroacetyl group are susceptible to hydrolysis as a further step in degradation. In terrestrial field dissipation studies conducted with application rates of 0.75 to 0.8 pounds per acre in eight sites with a range of soil types, furilazole dissipated readily with an average DT<sub>50</sub> of about 13 days. This low persistence in the environment combined with the low application rate (maximum of 0.4 pound per acre) indicates that furilazole is not likely to be present in ground water. Based on these considerations, Monsanto does not anticipate exposure to residues of furilazole in drinking water. EPA has not established a Maximum Concentration Level (MCL) or a health

advisory level for residues of furilazole in drinking water.

2. *Non-dietary exposure*. Furilazole is used only as a safener or antidote to the effects of acetochlor herbicide on corn seed or seedlings. It is sold only as part of acetochlor herbicide end-use products which are classified as Restricted Use by EPA which means they are used only by certified applicators and are not available to the general public. Herbicide products containing furilazole are not registered for residential, home owner, or other non-crop uses. They are thus not used in parks, school grounds, public buildings, roadsides or rights-of-way or other public areas. Commercial cornfields are generally located well away from public areas where incidental contact could occur. Therefore, the general public is very unlikely to have any non-dietary exposure to furilazole.

#### D. Cumulative Effects

Monsanto has no reliable data or information to suggest that furilazole has toxic effects that arise from toxic mechanisms that are common to other substances. Therefore, a consideration of common toxic mechanism and cumulative effects with other substances is not appropriate for furilazole, and Monsanto is considering only the potential effects of furilazole in this aggregate exposure assessment.

#### E. Safety Determination

1. *U.S. population*—i. *Chronic risk*. The conservative estimate of aggregate chronic exposure is  $3.0 \times 10^{-6}$  mg/kg/day. This potential exposure represents only 0.12% of the RfD of 0.0026 mg/kg/day and provides a MOE of 1,666,667 when compared to the 5 mg/kg/day carcinogenic reference point. EPA generally has no concern for exposures below 100% of the RfD and there are adequate margins of safety for cancer. Monsanto concludes there is a reasonable certainty of no harm resulting from exposure to furilazole.

2. *Infants and children*. Employing the same conservative TMRC estimates of exposure used in the risk assessment for the general population, Monsanto has calculated that the aggregate exposures for nursing infants, non-nursing infants, children age 1-6 and children age 7-12 are less than 0.4% of the RfD for each group. EPA generally has no concern for exposures below 100% of the RfD.

Monsanto notes the developmental toxicity NOAEL for rats (10 mg/kg/day) is 38.5-fold higher than the NOAEL of 0.26 mg/kg/day in the chronic rat study on which the RfD is based. This

indicates that the RfD is adequate for assessing risk to children. Also, the developmental toxicity NOAEL of 10 mg/kg/day is the same as the NOAEL for maternal toxicity, indicating that offspring are not more sensitive than parents.

In the 2-generation rat reproduction study, the NOAEL for reproductive toxicity and offspring survival was 101 mg/kg/day. This is 388-fold higher than the NOAEL for chronic toxicity upon which the RfD is based. The NOAEL for pup toxicity was no higher than the NOAEL for parental toxicity, indicating there is no unique sensitivity for offspring to furilazole.

Monsanto believes that these data do not indicate an increased prenatal or postnatal sensitivity of children and infants to furilazole exposure and concludes that the 100-fold uncertainty factor used in the RfD is adequate to protect infants and children.

#### *F. International Tolerances*

The Codex Alimentarius Commission has not established a maximum residue level for furilazole.

[FR Doc. 99-27395 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6461-2]

### Notice of Availability of Letter From EPA to the State of Minnesota Pursuant to Section 118 of the Clean Water Act and the Water Quality Guidance for the Great Lakes System

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability.

**SUMMARY:** Notice is hereby given that Region 5 of the Environmental Protection Agency (EPA) proposes to find that the State of Minnesota (Minnesota) has fulfilled its obligation under section 118(c) of the Clean Water Act and 40 CFR part 132 by adopting provisions in its water quality standards and National Pollutant Discharge Elimination System (NPDES) permits program that EPA believes are consistent with section 118(c) of the Clean Water Act (CWA) and 40 CFR part 132. The basis for EPA's belief and its proposed course of action are described in a September 28, 1999 letter from Region 5 to the State. EPA invites public

comment on all aspects of that letter and on EPA's proposed course of action.

**DATES:** Comments must be received in writing by December 6, 1999.

**ADDRESSES:** Written comments may be submitted to Joan M. Karnauskas, Chief, Standards and Applied Sciences Branch (WT-15J), Water Division, U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard., Chicago, Illinois, 60604. In the alternative, EPA will accept comments electronically. Comments should be sent to the following Internet E-mail address: karnauskas.joan@epamail.epa.gov. Electronic comments must be submitted in an ASCII file avoiding the use of special characters and any form of encryption. EPA will print electronic comments in hard-copy paper form for the official administrative record. EPA will attempt to clarify electronic comments if there is an apparent error in transmission. Comments provided electronically will be considered timely if they are submitted electronically by 11:59 p.m. (Eastern time) December 6, 1999.

**FOR FURTHER INFORMATION CONTACT:** Joan M. Karnauskas, Standards and Applied Sciences Branch (WT-15J), Water Division, U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, or telephone her at (312) 886-6090.

Copies of the September 28, 1999 letter described above are available upon request by contacting Ms. Karnauskas. The September 28, 1999 letter and materials submitted by Minnesota in support of its submission that EPA relied upon in preparing the letter (i.e., the docket) are available for review by appointment at: EPA, Region 5, 77 W Jackson Boulevard, Chicago, Illinois (telephone 312-886-3717); and Minnesota Pollution Control Agency, 520 Lafayette Road N., St. Paul, Minnesota (telephone 651-296-3000). To access the docket material in Chicago, call Ms. Mary Willis at (312) 886-3717 between 8 a.m. and 4:30 p.m. (central time) (Monday-Friday); in Minnesota, call Mr. Gary Kimball at (651) 297-8221 between 8 a.m. and 4:30 p.m. (central time).

**SUPPLEMENTARY INFORMATION:** On March 23, 1995, EPA published the Final Water Quality Guidance for the Great Lakes System (Guidance) pursuant to section 118(c)(2) of the Clean Water Act, 33 U.S.C. 1268(c)(2). (March 23, 1995, 60 FR 15366). The Guidance, which was

codified at 40 CFR part 132, requires the Great Lakes States to adopt and submit to EPA for approval water quality criteria, methodologies, policies and procedures that are consistent with the Guidance. 40 CFR 132.4 and 132.5. EPA is required to approve of the State's submission within 90 days or notify the State that EPA has determined that all or part of the submission is inconsistent with the Clean Water Act or the Guidance and identify any necessary changes to obtain EPA approval. If the State fails to make the necessary changes within 90 days, EPA must publish a notice in the **Federal Register** identifying the approved and disapproved elements of the submission and a final rule identifying the provisions of Part 132 that shall apply for discharges within the State.

EPA reviewed the submission from Minnesota for consistency with the Guidance in accordance with 40 CFR part 131 and 132.5. Based on its review to date, EPA believes that Minnesota has adopted provisions that are consistent with the Guidance. The basis for EPA's belief is set forth in the September 28, 1999 letter. Today, EPA is soliciting public comment regarding all aspects of that letter and on EPA's belief that Minnesota has adopted provisions that are consistent with the Guidance.

EPA intends to review any information provided to it within the next 45 days before taking further action pursuant to section 118(c) of the Clean Water Act and 40 CFR part 132 on Minnesota's submission.

**Elissa Speizman,**

*Acting Regional Administrator, Region 5.*

[FR Doc. 99-27385 Filed 10-19-99; 8:45 am]

BILLING CODE 6560-50-P

## FEDERAL COMMUNICATIONS COMMISSION

### Sunshine Act Meeting

October 14, 1999.

### Open Commission Meeting, Thursday, October 21, 1999

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, October 21, 1999, which is scheduled to commence at 9:30 a.m. in Room TW-C305, at 445 12th Street, S.W., Washington, D.C.

Item No.	Bureau	Subject
1 .....	Common Carrier .....	TITLE: Federal-State Joint Board on Universal Service (CC Docket No. 96-45).

Item No.	Bureau	Subject
2 .....	Common Carrier .....	SUMMARY: The Commission will consider reforming its high-cost universal service support mechanism for non-rural carriers. TITLE: Federal-State Joint Board on Universal Service (CC Docket No. 96-45); and Forward-Looking Mechanism for High Cost Support for Non-Rural LECs (CC Docket No. 97-160). SUMMARY: The Commission will consider input values to be used in the forward-looking cost model to estimate universal service high-cost support for non-rural carriers.
3 .....	Mass Media and Office of Engineering and Technology .....	TITLE: Digital Audio Broadcasting Systems and Their Impact on the Terrestrial Radio Broadcast Service. SUMMARY: The Commission will consider a Notice of Proposed Rulemaking concerning the introduction of digital audio broadcasting.
4 .....	Engineering and Technology .....	TITLE: Amendment of Parts 2 and 90 of the Commission's Rules to Allocate the 5.850-5.925 GHz Band to the Mobile Service for Dedicated Short Range Communications of Intelligent Transportation Services (ET Docket No. 98-95, RM-9096). SUMMARY: The Commission will consider a Report and Order to allocate the 5.850-5.925 GHz band for Intelligence Transportation Service.

Additional information concerning this meeting may be obtained from Maureen Peratino or David Fiske, Office of Public Affairs, telephone number (202) 418-0500; TTY (202) 418-2555.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, International Transcription Services, Inc. (ITS, Inc.) at (202) 857-3800; fax (202) 857-3805 and 857-3184; or TTY (202) 293-8810. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio tape. ITS may be reached by e-mail: [its\\_inc@ix.netcom.com](mailto:its_inc@ix.netcom.com). Their Internet address is <http://www.itsi.com>.

This meeting can be viewed over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. For information on these services call (703) 993-3100. The audio portion of the meeting will be broadcast live on the Internet via the FCC's Internet audio broadcast page at <http://www.fcc.gov/realaudio/>. The meeting can also be heard via telephone, for a fee, from National Narrowcast Network, telephone (202) 966-2211 or fax (202) 966-1770. Audio and video tapes of this meeting can be purchased from Infocus, 341 Victory Drive, Herndon, VA 20170, telephone (703) 834-0100; fax number (703) 834-0111.

Federal Communications Commission.

**Magalie Roman Salas,**  
Secretary.

[FR Doc. 99-27517 Filed 10-18-99; 1:06 pm]

BILLING CODE 6712-01-M

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meeting

**AGENCY:** Federal Election Commission.  
**DATE AND TIME:** Tuesday, October 26, 1999 at 10 a.m.

**PLACE:** 999 E Street, NW., Washington, DC.

**STATUS:** This meeting will be closed to the public.

#### ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.  
Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.  
Matters concerning participation in civil actions or proceedings or arbitration.  
Internal personnel rules and procedures or matters affecting a particular employee.

**DATE AND TIME:** Thursday, October 28, 1999 at 10 a.m.

**PLACE:** 999 E Street, NW., Washington, DC (ninth floor).

**STATUS:** This meeting will be open to the public.

#### ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.  
Advisory Opinion 1999-17: Governor George W. Bush for President Exploratory Committee by counsel, Benjamin Ginsberg.  
Advisory Opinion 1999-27: Alaska Federation of Republican Women by counsel, Timothy A. McKeever.  
Advisory Opinion 1999-28: Bacardi-Martini, USA, Inc. by counsel, Bobby Burchfield.  
Notice of Inquiry—Internet/FECA issues.

Administrative Matters.

#### PERSON TO CONTACT FOR INFORMATION:

Mr. Ron Harris, Press Officer,  
Telephone: (202) 694-1220.

**Mary W. Dove,**  
Acting Secretary.

[FR Doc. 99-27554 Filed 10-18-99; 2:35 pm]

BILLING CODE 6715-01-M

## FEDERAL RESERVE SYSTEM

### Federal Open Market Committee; Domestic Policy Directive of August 24, 1999.

In accordance with § 271.5 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on August 24, 1999.<sup>1</sup> The directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting suggests continued solid expansion of economic activity. Nonfarm payroll employment has increased rapidly in recent months, and the civilian unemployment rate, at 4.3 percent in July, matched its average for the first half of the year. Manufacturing output continued to grow moderately on average in June and July. Total retail sales have grown less rapidly in recent months, while housing activity has

<sup>1</sup> Copies of the Minutes of the Federal Open Market Committee meeting of August 24, 1999, which include the domestic policy directive issued at that meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

remained robust. Available indicators suggest that the expansion in business capital spending has slackened somewhat after a surge this spring. The nominal deficit on U.S. trade in goods and services widened substantially in the second quarter. Consumer price inflation has been boosted in recent months by an appreciable rise in energy prices; against the background of very tight labor markets, increases in wages and total compensation have been somewhat larger.

Most interest rates are little changed on balance since the meeting on June 29-30, 1999. Key measures of share prices in equity markets have posted mixed changes over the intermeeting period. In foreign exchange markets, the trade-weighted value of the dollar has declined slightly over the period in relation to the currencies of a broad group of important U.S. trading partners.

M2 and M3 have grown at a moderate pace in recent months. For the year through July, M2 is estimated to have increased at a rate somewhat above the Committee's annual range and M3 at a rate approximating the upper end of its range. Total domestic nonfinancial debt has continued to expand at a pace somewhat above the middle of its range.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee reaffirmed at its meeting in June the ranges it had established in February for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1998 to the fourth quarter of 1999. The range for growth of total domestic nonfinancial debt was maintained at 3 to 7 percent for the year. For 2000, the Committee agreed on a tentative basis in June to retain the same ranges for growth of the monetary aggregates and debt, measured from the fourth quarter of 1999 to the fourth quarter of 2000. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

To promote the Committee's long-run objectives of price stability and sustainable economic growth, the Committee in the immediate future seeks conditions in reserve markets consistent with increasing the federal funds rate to an average of around 5-1/4 percent. In view of the evidence currently available, the Committee believes that prospective developments are equally likely to warrant an increase

or a decrease in the federal funds rate operating objective during the intermeeting period.

By order of the Federal Open Market Committee, October 13, 1999.

**Donald L. Kohn,**

*Secretary, Federal Open Market Committee.*

[FR Doc. 99-27315 Filed 10-19-99; 8:45 am]

BILLING CODE 6210-01-F

## FEDERAL RESERVE SYSTEM

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Board of Governors of the Federal Reserve System.

**TIME AND DATE:** 11:00 a.m., Monday, October 25, 1999.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

**STATUS:** Closed.

#### MATTERS TO BE CONSIDERED:

1. Proposed Federal Reserve check automation strategy.

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Lynn S. Fox, Assistant to the Board; 202-452-3204.

**SUPPLEMENTARY INFORMATION:** You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 15, 1999.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 99-27458 Filed 10-18-99; 10:41 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary, DHHS

#### Request for Nominations for the Secretary's Advisory Committee on Xenotransplantation

**ACTION:** Notice.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), the Department of Health and Human Services (DHHS) is announcing the establishment of the Secretary's Advisory Committee on Xenotransplantation (SACX) and is soliciting nominations for qualified individuals to serve on the SACX.

**DATES:** Nomination packages should be submitted to Dr. Mary Groesch, Office of Biotechnology Activities, Office of Science Policy, National Institutes of Health, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010 by December 6, 1999.

**FOR FURTHER INFORMATION CONTACT:** Dr. Mary Groesch, Office of Biotechnology Activities, Office of Science Policy, National Institutes of Health, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, telephone 301-496-0785, facsimile 301-496-9839, e-mail [groeschm@od.nih.gov](mailto:groeschm@od.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

Xenotransplantation involves use of live cells, tissues, or organs from a nonhuman animal source transplanted or implanted into a human or used for ex vivo contact with human body fluids, cells, tissues or organs that are subsequently given to a human recipient. Interest in xenotransplantation has been renewed by the continuing, critical shortage of donated human organs and by advances in immunology and in the biology of organ and tissue rejection. Xenotransplantation holds potential for the treatment of a wide range of conditions and disorders, including diabetes, Parkinson's disease, intractable pain, and other diseases involving tissue destruction and organ failure. However, xenotransplantation research also poses certain challenges with respect to the potential for transmission of infectious agents from animal donors to human recipients.

Public awareness and understanding of xenotransplantation is vital because the infectious disease risks posed by xenotransplantation could extend beyond the individual patients to the public at large. In addition to these safety issues, a number of individuals and groups have raised concerns about the implications of xenotransplantation for human rights, community interest and consent, social equity in access to novel biotechnologies, allocation of human allografts, and animal welfare. For all of these reasons, scientific review of and public discourse on

xenotransplantation research are critical and necessary.

The Secretary, DHHS, has established the Secretary's Advisory Committee on Xenotransplantation to provide a forum for the discussion of, and public input on, these and other relevant issues.

### **Abridged Committee Charter**

#### *Purpose*

The DHHS has a vital role in safeguarding public health while fostering the development of promising strategies to treat tissue destruction, organ failure and other public health needs. The Secretary's Advisory Committee on Xenotransplantation considers the full range of complex scientific, medical, social, and ethical issues and the public health concerns raised by xenotransplantation, including ongoing and proposed protocols, and makes recommendations to the Secretary on policy and procedures. The recommendations of the Committee will facilitate DHHS efforts to develop an integrated approach to addressing emerging public health issues in xenotransplantation.

#### *Function*

The Secretary's Advisory Committee on Xenotransplantation shall advise the Secretary, through the Assistant Secretary for Health, on all aspects of the scientific development and clinical application of xenotransplantation. The Committee's charge includes the following activities:

- Advise the Department on the current state of knowledge regarding xenotransplantation.
- Review current and proposed xenotransplantation clinical trials. Identify and discuss the medical, scientific, ethical, legal, and/or socioeconomic issues raised by these clinical trials.
- Advise the Department on the potential for transmission of infectious diseases as a consequence of xenotransplantation.
- Recommend to the Department, as needed, changes to the PHS Guideline on Infectious Disease Issues in Xenotransplantation.
- Discuss additional scientific, medical, public health, ethical, legal and socioeconomic issues, including international policies and developments, that are relevant to xenotransplantation.

#### *Structure*

The Committee shall consist of 15 voting members, including the Chair, appointed by the Secretary or designee. Members shall be selected by the

Secretary, or designee, from authorities knowledgeable in such fields as xenotransplantation, epidemiology, virology, microbiology, infectious diseases, molecular biology, veterinary medicine, immunology, transplantation surgery, public health, applicable law, bioethics, social sciences, psychology, patient advocacy, and animal welfare. Of the appointed members, at least one shall be a current member of the Xenotransplantation Subcommittee of the Food and Drug Administration (FDA) Biologic Response Modifiers Advisory Committee and at least one shall be a current member of the Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee.

In addition, the Committee shall include non-voting, *ex officio* members from relevant DHHS components, including the Office of the Secretary, CDC, FDA, Health Resources and Services Administration, National Institutes of Health and others as deemed appropriate by the Secretary or designee. As necessary, standing and ad hoc subcommittees composed of members of the parent committee may be established to perform specific functions within the Committee's jurisdiction.

Members shall be invited to serve for overlapping four year terms; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. The Committee shall be able to call upon special consultants, assemble ad hoc working groups and convene conferences and workshops as necessary to assist in the work of the Committee. Management and support services shall be provided by the Office of Science Policy, Office of the Director, National Institutes of Health, with direction and guidance from the Assistant Secretary for Health.

#### *Meetings*

Meetings shall be held approximately three times per year at the call of the Chair with the advance approval of a Government official who shall also approve the agenda. A Government official shall be present at all meetings. Meetings shall be open to the public except as determined otherwise by the Secretary or designee; notice of all meetings shall be provided to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

#### **Nominations**

DHHS will consider nominations of all qualified individuals. Committee

members will have expertise in such fields as xenotransplantation, epidemiology, virology, microbiology, infectious diseases, molecular biology, veterinary medicine, immunology, transplantation surgery, public health, law, bioethics, social sciences, psychology, patient advocacy, and animal welfare. Individuals may nominate themselves or other individuals, and professional associations and other organizations may nominate individuals.

DHHS has a strong interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the Committee and, therefore, encourages nominations of qualified candidates from these groups. DHHS also encourages geographic diversity in the composition of the Committee.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes recommend him/her for service in this capacity), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his or her curriculum vitae; and (3) the name, return address, and daytime telephone number at which the nominator can be contacted. Optimally, a nomination package would also include a statement by the nominee that he/she is willing to accept an appointment to Committee membership.

All nomination information should be provided in a single, complete package within 45 days of the publication of this notice. The nomination letter should bear an original signature; facsimile transmissions or copies cannot be accepted. All nominations for membership should be sent to Dr. Mary Groesch at the address provided above.

Dated: October 13, 1999.

**David Satcher,**

*Assistant Secretary for Health and Surgeon General.*

[FR Doc. 99-27306 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Submission for OMB Review; Comment Request**

*Title:* Online Interstate Referral Guide (IRG).

*OMB No.:* New.

*Description:* The IRG is an essential reference maintained by the Federal Office of Child Support Enforcement (OCSE) that provides State IV-D agencies with the information needed to process interstate cases. The Online

version of the IRG will provide States with an effective and efficient way of viewing and updating State profile, address, and FIPS code information by consolidating data available through

numerous discrete sources into a single centralized, automated repository.

*Respondents:* State, Local or Tribal Governments.

*Annual Burden Estimates:*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Online IRG .....	54	18	.3	292

*Estimated Total Annual Burden Hours:* 292.

#### Additional Information

Copies of the proposed collection may be requested by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

#### 9OMB comment

OMB is required to make a decision concerning the collection of information between 30 to 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, 725 17th Street, NW, Washington, DC 20503, Attn: ACF Desk Officer.

Dated: October 14, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

[FR Doc. 99-27375 Filed 10-19-99; 8:45 am]

BILLING CODE 4184-01-M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 99N-4236]

#### Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 15, 1999, from 8 a.m. to 5:30 p.m., and on November 16, 1999, from 8 a.m. to 1 p.m. Interested persons and organizations may submit written comments by November 8, 1999, to the Dockets Management Branch (address below).

*Location and Addresses:* Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Contact:* Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6767, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will discuss broad pediatric issues as recommended in the final rule entitled "Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biologic Products in Pediatric Patients" (63 FR 66632, December 2, 1998).

On November 15, 1999, the subcommittee will discuss ethical considerations in the conduct of pediatric clinical trials involving a drug or biologic product, specifically the role of pediatric subjects/volunteers who do not have the disease under study.

On November 16, 1999, the subcommittee will discuss whether or not there is a public health need for the pharmaceutical industry to extend their drug development program for sleep disorders into the pediatric population.

In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing data, information, and views relevant to the agenda items. These submissions should contain the docket number 99N-4236 and be submitted to the Dockets Management Branch (address above).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 8, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on November 15, 1999, and between approximately 10:30 a.m. and 11 a.m. on November 16, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 12, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-27419 Filed 10-19-99; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

#### Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Dermatologic and Ophthalmic Drugs Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on November 4 and 5, 1999, 8:30 a.m. to 5:30 p.m.

**Location:** Hilton Hotel, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD 20877, 301-977-8900.

**Contact Person:** Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet FDA Website at [www.fda.gov](http://www.fda.gov).

**Agenda:** On November 4, 1999, during the morning session, the committee will discuss new drug application (NDA) 21-022, Loprox™ (ciclopirox nail lacquer), Hoechst Marion Roussel, Inc., for treatment of onychomycosis. On November 4, 1999, during the afternoon session, the committee will participate in a scientific discussion of clinical trial design questions for products intended for the treatment of hand dermatitis. On November 5, 1999, during the afternoon session, the committee will discuss NDA 20-965, Levulan® (aminolevulinic acid HCL) Kerastick™ for Topical Solution, 20 percent, Dusa Pharmaceuticals, Inc., for use in the treatment of multiple actinic keratoses of the face and scalp.

**Procedure:** On November 4, 1999, from 8:30 a.m. to 5:30 p.m. and on November 5, 1999, from 1 p.m. to 5:30 p.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be made to the contact person by October 29, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. and between approximately 1 p.m. and 1:30 p.m. on November 4, 1999. Time allotted for each presentation may be limited. Those desiring to make oral presentations should notify the contact person before October 29, 1999, and submit a brief statement of the general nature of the evidence or arguments

they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

**Closed Committee Deliberations:** On November 5, 1999, from 8:30 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding pending NDA's issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 12, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 99-27418 Filed 10-19-99; 8:45 am]

BILLING CODE 4160-01-F

## 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. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Special Emphasis Panel In Vivo Cellular and Molecular Imaging Centers (Pre-ICMICs/ICMICs).

**Date:** November 8-10, 1999.

**Time:** 8:00 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Ramanda Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

**Contact Person:** Lalita D Palekar, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN-622B, Rockville, MD 20892-7405, 301/496-7505.

**Name of Committee:** National Cancer Institute Special Emphasis Panel Therapeutic Modulation of Angiogenesis in Disease.

**Date:** November 15-17, 1999.

**Time:** 7:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** Lalita D. Palekar, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN-622B, Rockville, MD 20892-7405, 301/496-7575.

(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 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27330 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Special Emphasis Panel, Special Populations Networks for Cancer Awareness Research and Training.

**Date:** November 18-19, 1999.

**Time:** 8 am to 6 pm.

**Agenda:** To review and evaluate grant applications.

**Place:** Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** Joyce C. Pegues, Scientific Review Administrator, Special Review, Referral, and Resources Branch, Division of Extramural Activities, National Cancer Institutes, 6130 Executive Boulevard, Room EPN-609, Bethesda, MD 20892, 301/496-2378.

(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 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27340 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Special Emphasis Panel.

*Date:* November 17-19, 1999.

*Time:* 7 pm to 12 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

*Contact Person:* Sherwood Githens, Scientific Review Administrator, National Institutes of Health, National Cancer Institute, Special Review, Referral and Resources Branch, Executive Plaza North, 6130 Executive Boulevard, Bethesda, MD 20892, 301/435-9050.

(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 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27341 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Initial Review Group, Subcommittee F—Manpower & Training.

*Date:* November 17-19, 1999.

*Time:* November 17, 1999, 6:30 pm to 8 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

*Contact Person:* Mary Bell, Health Scientist Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, PHS, DHHS, Rockville, MD 20892.

(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 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27342 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provision set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C. The discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and the premature disclosure of discussions related to personnel and confidential administrative information would be likely to significantly frustrate the subsequent implementation of recommendations.

*Name of Committee:* National Cancer Institute Board of Scientific Advisors.

*Date:* November 8-9, 1999.

*Open:* November 8, 8:30 am to 5 pm; November 9, 8:30 am to 12 pm.

*Agenda:* Report of the Director, NCI; Ongoing and New Business, Reports of Program Review Group(s), Budget Presentation, Reports of Special Initiatives, and RFA Concept Reviews.

*Closed:* November 8, 5 pm to 6 pm.

*Agenda:* To review and evaluate personnel and programmatic issues.

*Place:* National Cancer Institutes, 9000 Rockville Pike, Building 31, C Wing, 6 Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Paulette S. Gray, Executive Secretary, Deputy Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Executive Plaza North, Suite 600, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496-4218.

(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 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory  
Committee Policy, NIH.*

[FR Doc. 99-27343 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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:* Heart, Lung, and Blood Program Project Review Committee.

*Date:* December 2, 1999.

*Time:* 8 am to 4 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Jeffrey H. Hurst, Scientific Review Administrator, Review Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301/435-0303.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 99-27339 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 material, 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 of Neurological Disorders and Stroke Special Emphasis Panel.

*Date:* November 3, 1999.

*Time:* 1 pm to 3 pm.

*Agenda:* To Review and evaluate contract proposals

*Place:* Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Phillip F. Wiethorn, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 99-27331 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## 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. Appendix 2), 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 Drug Abuse Special Emphasis Panel, Minority Institutions Drug Abuse Research Development Program.

*Date:* November 1, 1999.

*Time:* 10 am to 1 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

*Contact Person:* Marina L. Volkov, Special Expert, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892-9547, (301) 435-1433.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 99-27332 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## 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. Appendix 2), 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 material, 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, "Technical and Logistical Support Assistance to the Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA)".

*Date:* October 21, 1999.

*Time:* 9:30 am to 11 am.

*Agenda:* To review and evaluate contract proposals.

*Place:* Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

*Contact Person:* Eric Zatman, Contract Review Specialist, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892-9547, (301) 435-1438.

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. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

*Dated:* October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27334 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Diabetes, Endocrinology and Metabolic Diseases B Subcommittee, October 29, 1999, 8 am to October 29, 1999, 5 pm, Double Tree Hotel, 1750 Rockville Pike, Rockville, MD, 20852 which was published in the **Federal Register** on September 14, 1999, 64 FR 49815.

The meeting is being amended to add the Open Session. The meeting will have an Open Session on October 28, 1999 from 5:30 p.m. until 7:00 p.m. the meeting is partially Closed to the public.

*Dated:* October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27335 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Kidney, Urologic and Hematologic Diseases D Subcommittee, October 29, 1999, 8 am to October 29, 1999, 5 pm, Double Tree Hotel, 1750 Rockville Pike, Rockville, MD, 20852 which was published in the **Federal Register** on September 14, 1999, 64 FR 49815.

The meeting is being amended to add the Open Session. The meeting will have an Open Session on October 28, 1999 from 5:30 p.m. until 7:00 p.m. The meeting is partially Closed to the public.

*Dated:* October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27336 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Digestive Diseases and Nutrition C. Subcommittee, October 29, 1999, 8 am to October 29, 1999, 5 pm, Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852 which was published in the **Federal Register** on September 14, 1999, 64FR49815.

The meeting is being amended to add the Open Session. The meeting will have an Open Session on October 28, 1999 from 5:30 p.m. until 7:00 p.m. The meeting is partially Closed to the public.

*Dated:* October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27337 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## 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. Appendix 2), notice is hereby given of a meeting of the Advisory Committee on Research on Women's Health.

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:* Advisory Committee on Research on Women's Health.

*Date:* November 15, 1999.

*Time:* 8:30 am to 5 pm.

*Agenda:* To provide advice on appropriate research activities with respect to women's health and related studies to be undertaken by the national research institutes, to provide recommendations regarding ORWH activities, and to assist in monitoring compliance regarding the inclusion of women in clinical research.

*Place:* National Institutes of Health, Building 31, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Joyce Rudick, Director, Programs & Management, Office of Research on Women's Health, Office of the Director, National Institutes of Health, Building 1, Room 201, Bethesda, MD 20892, 301/402-1770.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 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, National Institutes of Health, HHS)

*Dated:* October 13, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-27338 Filed 10-19-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

[NV-065-1640-00]

## Notice of Emergency Closure of Public Lands; Nye County, NV

**AGENCY:** Bureau of Land Management, Interior.

**SUMMARY:** Notice is hereby given that certain public lands in the vicinity of Tybo Canyon, Nye County Nevada, are temporarily closed to the public. The closure includes entry upon the subject lands for the purposes of mineral exploration and staking. This closure is necessary to provide for public safety due to the discovery of hazardous materials within the following described public lands:

**T. 6 N., R. 50 E.**

Sec. 17, SE ¼;

Sec. 16, NE¼ NW¼;

Sec. 9, SE¼ NE¼; NE¼ SE¼; SW¼ SE¼;

Sec. 10, N½ N½;

Containing 520 acres, more or less.

**EFFECTIVE DATES:** This closure goes into effect on October 7, 1999, and will remain in effect until the Assistant Field Manager, Tonopah Field Station, determines the closure is no longer needed.

**FOR FURTHER INFORMATION CONTACT:**

Terry Neumann, Tonopah Field Station, 1553 South Main Street, Tonopah, NV 89049. Telephone (775) 482-7800.

**Authority:** The authority for this closure is 43 CFR 8364.1. Any person who fails to comply with a closure order is subject to arrest and fines and/or imprisonment not to exceed 12 months in accordance with applicable provisions of 18 USC 3571. This closure applies to all persons excluding (1) public officials and emergency and law enforcement personnel engaged in official business and (2) any person expressly authorized in writing by the Assistant Field Manager, Tonopah, to enter the closed area. The closure area is posted and a map of the closure area is posted in the Tonopah Post Office.

Dated: October 7, 1999.

**W. Craig MacKinnon,**

*Assistant Field Manager, Tonopah.*

[FR Doc. 99-27310 Filed 10-19-99; 8:45 am]

BILLING CODE 4310-HC-P

## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

[CO-010-07-1020-00-241A]

## Northwest Colorado Resource Advisory Council Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** The next meeting of the Northwest Colorado Resource Advisory Council will be held on Friday, December 3, 1999, at the Garfield County Courthouse in Glenwood Springs, Colorado.

**DATES:** Friday, December 3, 1999.

**ADDRESSES:** For further information, contact Lynn Barclay, Bureau of Land Management (BLM), 455 Emerson Street, Craig, Colorado 81625; Telephone (970) 826-5096.

**SUPPLEMENTARY INFORMATION:** The Northwest Resource Advisory Council will meet on Friday, December 3, 1999, at the Garfield County Courthouse, Suite 302, 109 8th Street, Glenwood Springs, Colorado. The meeting will start at 9 a.m. and include election of officials and goal setting for the Northwest Colorado Resource Advisory Council; and discussions of the proposed statewide recreation guidelines, Kremmling Field Office Planning Amendments, and Craig Field Office Fire Management Planning.

The meeting is open to the public. Interested persons may make oral statements at the meetings or submit written statements at the meeting. Per-person time limits for oral statements may be set to allow all interested persons an opportunity to speak.

Summary minutes of council meetings are maintained at the Bureau of Land Management Offices in Grand Junction and Craig, Colorado. They are available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting.

Dated: October 13, 1999.

**Mark T. Morse,**

*Center Manager, Northwest Center.*

[FR Doc. 99-27413 Filed 10-19-99; 8:45 am]

BILLING CODE 4310-70-P

## OVERSEAS PRIVATE INVESTMENT CORPORATION

## Submission for OMB Review; Comment Request

**AGENCY:** Overseas Private Investment Corporation.

**ACTION:** Request for comments.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the Agency is preparing an information collection request for OMB review and approval and to request public review and

comment on the submission. Comments are being solicited on the need for the information, its practical utility, the accuracy of the Agency's burden estimate, and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review is summarized below.

**DATES:** Comments must be received by December 20, 1999.

**ADDRESSES:** Copies of the subject form and the request for review prepared for submission to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the Agency Submitting Officer.

**FOR FURTHER INFORMATION CONTACT:**

*OPIC Agency Submitting Officer:* Carol Brock, Records Manager, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; 202/336-8563.

**SUMMARY OF FORM UNDER REVIEW:**

*Type of Request:* Approval of a revised form combining two forms, one for U.S. and one for foreign sponsors, OPIC-129 (OMB 3420-0018), which expires 10/31/99 and OPIC-130 (OMB 3420-0017) which expires 11/30/99, respectively. Three months expiration date extensions are being processed.

*Title:* Sponsor Disclosure Report.

*Form Number:* OPIC-129.

*Frequency of Use:* Once per significant investor per project.

*Type of Respondents:* Business or other institutions and individuals.

*Standard Industrial Classification Codes:* All.

*Description of Affected Public:* U.S. companies or citizens investing overseas.

*Reporting Hours:* 6 hours per project.

*Number of Responses:* 122.5 per year.

*Federal Cost:* \$9,800 per year.

*Authority for Information Collection:*

Sections 231, 234 (b) and (c) of the Foreign Assistance Act of 1961, as amended.

*Abstract (Needs and Uses):* The Sponsor Disclosure Report is the principal document used by OPIC to gather information from project sponsors on whether a project might harm the U.S., and describes sponsor activities with the U.S. Government and other information for the underwriting and analysis of a project. It also provides notification of credit investigations that will be performed.

Dated: October 14, 1999.

**James R. Offutt,**

*Assistant General Counsel for Administrative Affairs, Department of Legal Affairs.*

[FR Doc. 99-27406 Filed 10-19-99; 8:45 am]

BILLING CODE 3210-01-P

**INTERNATIONAL TRADE COMMISSION****[Investigation No. 731-TA-811 (Final)]****Drams of One Megabit and Above From Taiwan; Notice of Commission Determination To Conduct a Portion of the Hearing in Camera****AGENCY:** U.S. International Trade Commission.**ACTION:** Closure of a portion of a Commission hearing.

**SUMMARY:** Upon request of respondent Taiwan Semiconductor Industry Association ("TSIA") and its member companies, the Commission has determined to conduct a portion of its hearing in the above-captioned investigation scheduled for October 19, 1999, in camera. See Commission rules 207.24(d), 201.13(m) and 201.36(b)(4) (19 CFR §§ 207.24(d), 201.13(m) and 201.36(b)(4)). The remainder of the hearing will be open to the public. The Commission has determined that the seven-day advance notice of the change to a meeting was not possible. See Commission rule 201.35(a), (c)(1) (19 CFR 201.35(a), (c)(1)).

**FOR FURTHER INFORMATION CONTACT:** Shara L. Aranoff, Office of the General Counsel, U.S. International Trade Commission, telephone 202-205-3090, e-mail saranoff@usitc.gov. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Commission's TDD terminal on 202-205-3105.

**SUPPLEMENTARY INFORMATION:** The Commission believes that TSIA has justified the need for a closed session. TSIA seeks a closed session to allow for a discussion of market share data; financial performance data of individual domestic producers including the petitioner, Micron; market trends data; and data regarding product differentiation and market segmentation on a company-specific basis. In making this decision, the Commission nevertheless reaffirms its belief that whenever possible its business should be conducted in public.

The hearing will begin with public presentations by the petitioner Micron Technology, Inc. and respondents, with questions from the Commission. In addition, the hearing will include a 15-minute in camera session for a confidential presentation by TSIA and for questions from the Commission relating to the BPI, followed by a 15-minute in camera rebuttal presentation by petitioner. For any in camera session the room will be cleared of all persons

except those who have been granted access to BPI under a Commission administrative protective order (APO) and are included on the Commission's APO service list in this investigation. See 19 CFR 201.35(b)(1), (2). The time for the parties' presentations and rebuttals in the in camera session will be taken from their respective overall allotments for the hearing. All persons planning to attend the in camera portions of the hearing should be prepared to present proper identification.

**Authority:** The General Counsel has certified, pursuant to Commission Rule 201.39 (19 CFR 201.39) that, in her opinion, a portion of the Commission's hearing in DRAMs of One Megabit and Above from Taiwan, Inv. No. 731-TA-811 (Final), may be closed to the public to prevent the disclosure of BPI.

Issued: October 15, 1999.

By order of the Commission.

**Donna R. Koehnke,***Secretary.*

[FR Doc. 99-27401 Filed 10-19-99; 8:45 am]

BILLING CODE 7020-02-P

**INTERNATIONAL TRADE COMMISSION****[Inv. No. 337-TA-372 (Enforcement Proceeding)]****Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same; Notice of Commission Decision Vacating an Order Imposing a Civil Penalty for Violation of a Consent Order and Dismissing Formal Enforcement Proceeding****AGENCY:** International Trade Commission.**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Commission has vacated its September 26, 1997, order imposing a civil penalty in the amount of \$1,550,000 on San Huan New Materials High Tech, Inc.; Ningbo Konit Industries, Inc.; and Tridus International, Inc. for violation of the consent order issued on October 11, 1995, and that the Commission has dismissed the formal enforcement proceeding instituted on May 16, 1996.

**FOR FURTHER INFORMATION CONTACT:** Michael Diehl, Office of the General Counsel, U.S. International Trade Commission, telephone 202-205-3095.

**SUPPLEMENTARY INFORMATION:** On October 11, 1995, the Commission terminated this investigation as to respondents San Huan New Materials

High Tech, Inc.; Ningbo Konit Industries, Inc.; and Tridus International, Inc. ("respondents") on the basis of a consent order. The order provided that respondents shall not sell for importation into the United States, import into the United States, or sell in the United States after importation neodymium-iron-boron magnets that infringe any of claims 1-3 of U.S. Letters Patent 4,588,439, (the "'439 patent"), except under consent or license from the complainant.

On March 6, 1996, complainant alleged that respondents were in violation of the consent order. The matter was referred to the administrative law judge ("ALJ") who presided over the original investigation, and on December 24, 1996, the ALJ issued a recommended determination ("RD") that respondents had violated the consent order, and that a civil penalty of \$1.625 million should be levied.

On September 26, 1997, the Commission determined that respondents had violated the consent order and assessed a civil penalty of \$1.55 million.

On June 8, 1999, complainant's successor in interest, YBM Magnex, Inc., and respondents executed an agreement providing a license for respondents to manufacture, import, and sell magnets covered by the '439 patent. On June 17, 1999, the parties filed a Joint Motion to Vacate the Commission's Civil Penalty Order. On June 29, 1999, the Commission's Office of Unfair Import Investigations ("OUII") filed its response to the joint motion. On July 9, 1999, respondents filed their Motion for Leave to File a Reply to OUII's Response to Joint Motion to Vacate the Commission's Civil Penalty Order, and attached the reply to the motion.

This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and section 210.76 of the Commission's Rules of Practice and Procedure (19 CFR 210.76).

Copies of the Commission's order and all other nonconfidential documents filed in connection with this proceeding are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-2000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal at 202-205-1810.

Issued: October 13, 1999.

By order of the Commission.

**Donna R. Koehnke,**

*Secretary.*

[FR Doc. 99-27400 Filed 10-10-99; 8:45 am]

BILLING CODE 7020-02-P

## DEPARTMENT OF JUSTICE

### Federal Bureau of Investigation

#### DNA Advisory Board Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given that the DNA Advisory Board (DAB) Statistics Subcommittee will meet on November 16, 1999, from 1 pm until 4 pm at The Double Tree Hotel, 300 Army Navy Drive, Arlington, Virginia, 22202. The DAB will meet on November 17, 1999, from 10 am until 4 pm at the Double Tree Hotel, 300 Army Navy Drive, Arlington, Virginia 22202. All attendees will be admitted only after displaying personal identification which bears a photograph of the attendee.

The DAB's scope of authority is: To develop, and if appropriate, periodically revise, recommended standards for quality assurance to the Director of the FBI, including standards for testing the proficiency of forensic laboratories, and forensic analysts, in conducting analysis of DNA; To recommend standards to the Director of the FBI which specify criteria for quality assurance and proficiency tests to be applied to the various types of DNA analysis used by forensic laboratories, including statistical and population genetics issues affecting the evaluation of the frequency of occurrence of DNA profiles calculated from pertinent population database(s); To recommend standards for acceptance of DNA profiles in the FBI's Combined DNA Index System (CODIS) which take account of relevant privacy, law enforcement and technical issues; and, To make recommendations for a system for grading proficiency testing performance to determine whether a laboratory is performing acceptably.

The topics to be discussed at the DAB Statistics Subcommittee meeting include mixtures, parentage and uniqueness. The topics to be discussed at the DAB meeting include: a review of minutes from the April 23, 1999, meeting; development of an audit document for the quality assurance standards, a discussion concerning privacy issues and a report and discussion of the statistics subcommittee meeting.

The meeting is open to the public on a first-come, first seated basis. Anyone

wishing to address the DAB must notify the Designated Federal Employee (DFE) in writing at least twenty-four hours before the DAB meeting. The notification must include the requestor's name, organizational affiliation, a short statement describing the topic to be addressed, and the amount of time requested. Oral statements to the DAB will be limited to five minutes and limited to subject matter directly related to the DAB's agenda, unless otherwise permitted by the Chairman.

Any member of the public may file a written statement for the record concerning the DAB and its work before or after the meeting. Written statements for the record will be furnished to each DAB member for their consideration and will be included in the official minutes of a DAB meeting. Written statements must be type-written on 8½" × 11" xerographic weight paper, one side only, and bound only by a paper clip (not stapled). All pages must be numbered. Statements should include the Name, Organizational Affiliation, Address, and Telephone number of the author(s). Written statements for the record will be included in minutes of the meeting immediately following the receipt of the written statement, unless the statement is received within three weeks of the meeting. Under this circumstance, the written statement will be included with the minutes of the following meeting. Written statements for the record should be submitted to the DFE.

Inquiries may be addressed to the DFE, Dr. Dwight E. Adams, Chief, Scientific Analysis Section, Laboratory Division—Room 3266, Federal Bureau of Investigation, 935 Pennsylvania Avenue, NW, Washington, DC 20535-0001, (202) 324-4416, FAX (202) 324-1462.

Dated: October 14, 1999.

**Dwight E. Adams,**

*Chief, Scientific Analysis Section, Federal Bureau of Investigation.*

[FR Doc. 99-27309 Filed 10-19-99; 8:45 am]

BILLING CODE 4410-02-P

## DEPARTMENT OF LABOR

### Office of the Secretary

#### Submission for OMB Review; Comment Request

October 13, 1999.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) review and approval in accordance with the Paperwork

Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor, Departmental Clearance Officer, Ira Mills ((202) 219-5096 ext. 143) or by E-Mail to Mills-Ira@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Officer of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395-7316) on or before November 19, 1999.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Agency:* Bureau of Labor Statistics.

*Title:* Point of Purchase Survey.

*OMB Number:* 1220-0044.

*Frequency:* Quarterly.

*Affected Public:* Individuals or households.

*Number of Respondents:* 17,827.

*Estimated Time Per respondent:* 11 minutes.

*Total Burden Hours:* 12,320.

*Total Annualized capital/startup costs:* \$0.

*Total annual costs (operating/maintaining systems or purchasing services):* \$0.

*Description:* The purpose of this collection is to develop and maintain a timely list of retail, wholesale, and service establishments at which people shop for specific consumer items. The information collected is used to select establishments for pricing market basket items as needed for the Consumer Price Index.

**Ira L. Mills,**

*Departmental Clearance Officer.*

[FR Doc. 99-27384 Filed 10-19-99; 8:45 am]

BILLING CODE 4510-24-M

**NATIONAL ARCHIVES AND RECORDS ADMINISTRATION****Records Schedules for Electronic Copies Previously Covered by General Records Schedule 20; Availability and Request for Comments**

**AGENCY:** National Archives and Records Administration, Office of Records Services—Washington, DC.

**ACTION:** Notice of availability of proposed records schedules; request for comments.

**SUMMARY:** The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal.

This request for comments pertains solely to schedules for electronic copies of records created using word processing and electronic mail where the recordkeeping copies are already scheduled. (Electronic copies are records created using word processing or electronic mail software that remain in storage on the computer system after the recordkeeping copies are produced.)

These records were previously approved for disposal under General Records Schedule 20, Items 13 and 14. Pursuant to NARA Bulletin 99-04, agencies must submit schedules for the electronic copies associated with program records and administrative records not covered by the General Records Schedules. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a). To facilitate review of these schedules, their availability for comment is announced in **Federal Register** notices separate from those used for other records disposition schedules.

**DATES:** Requests for copies must be received in writing on or before December 6, 1999. On request, NARA will send a copy of the schedule. NARA staff usually prepare appraisal

memorandums concerning a proposed schedule. These, too, may be requested. Requesters will be given 30 days to submit comments.

Some schedules submitted in accordance with NARA Bulletin 99-04 group records by program, function, or organizational element. These schedules do not include descriptions at the file series level, but, instead, provide citations to previously approved schedules or agency records disposition manuals (see **SUPPLEMENTARY INFORMATION** section of this notice). To facilitate review of such disposition requests, previously approved schedules or manuals that are cited may be requested in addition to schedules for the electronic copies. NARA will provide the first 100 pages at no cost. NARA may charge \$.20 per page for additional copies. These materials also may be examined at no cost at the National Archives at College Park (8601 Adelphi Road, College Park, MD).

**ADDRESSES:** To request a copy of any records schedule identified in this notice, write to the Life Cycle Management Division (NWML), National Archives and Records Administration (NARA), 8601 Adelphi Road, College Park, MD 20740-6001. Requests also may be transmitted by FAX to 301-713-6852 or by e-mail to records.mgt@arch2.nara.gov.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports and/or copies of previously approved schedules or manuals should so indicate in their request.

**FOR FURTHER INFORMATION CONTACT:** Marie Allen, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740-6001. Telephone: (301) 713-7110. E-mail: records.mgt@arch2.nara.gov.

**SUPPLEMENTARY INFORMATION:** Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs the records to conduct its business.

Routine administrative records common to most agencies are approved for disposal in the General Records Schedules (GRS), which are disposition schedules issued by NARA that apply Government-wide.

In the past, NARA approved the disposal of electronic copies of records created using electronic mail and word processing via General Records Schedule 20, Items 13 (word processing documents) and 14 (electronic mail). However, NARA has determined that a different approach to the disposition of electronic copies is needed. In 1998, the Archivist of the United States established an interagency Electronic Records Work Group to address this issue and pursuant to its recommendations, decided that agencies must submit schedules for the electronic copies of program records and administrative records not covered by the GRS. On March 25, 1999, the Archivist issued NARA Bulletin 99-04, which tells agencies what they must do to schedule electronic copies associated with previously scheduled program records and certain administrative records that were previously scheduled under GRS 20, Items 13 and 14.

Schedules submitted in accordance with NARA Bulletin 99-04 only cover the electronic copies associated with previously scheduled series. Agencies that wish to schedule hitherto unscheduled series must submit separate SF 115s that cover both recordkeeping copies and electronic copies used to create them.

In developing SF 115s for the electronic copies of scheduled records, agencies may use either of two scheduling models. They may add an appropriate disposition for the electronic copies formerly covered by GRS 20, Items 13 and 14, to every item in their manuals or records schedules where the recordkeeping copy has been created with a word processing or electronic mail application. This approach is described as Model 1 in Bulletin 99-04. Alternatively, agencies may group records by program, function, or organizational component and propose disposition instructions for the electronic copies associated with each grouping. This approach is described as Model 2 in the Bulletin. Schedules that follow Model 2 do not describe records at the series level.

For each schedule covered by this notice the following information is provided: name of the Federal agency and any subdivisions requesting disposition authority; the organizational unit(s) accumulating the records or a statement that the schedule has agency-wide applicability in the case of

schedules that cover records that may be accumulated throughout an agency; the control number assigned to each schedule; the total number of schedule items; the number of temporary items (the record series proposed for destruction); a brief description of the temporary electronic copies; and citations to previously approved SF 115s or printed disposition manuals that scheduled the recordkeeping copies associated with the electronic copies covered by the pending schedule. If a cited manual or schedule is available from the Government Printing Office or has been posted to a publicly available Web site, this too is noted.

Further information about the disposition process is available on request.

#### **Schedule Pending**

1. Department of Labor, Women's Bureau (N9-86-00-1, 5 items, 5 temporary items). Electronic copies of records created using electronic mail and word processing that relate to agency publications, speeches made by the Director or other designated staff members, informational releases, annual reports, and such issuances as organization charts and directives. This schedule follows Model 1 as described in the **SUPPLEMENTARY INFORMATION** section of this notice. Recordkeeping copies of these files are included in Disposition Job No. N1-86-90-1.

Dated: October 12, 1999.

**Michael J. Kurtz,**

*Assistant Archivist for Record Services—Washington, DC.*

[FR Doc. 99-27373 Filed 10-19-99; 8:45 am]

BILLING CODE 7515-01-P

#### **NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES**

##### **Sunshine Act Meeting; Meeting of the National Museum Services Board and the National Commission on Libraries and Information Science**

**AGENCY:** Institute of Museum and Library Services.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice sets forth the agenda of a forthcoming meeting of the National Museum Services Board and the National Commission on Libraries and Information Science. This notice also describes the function of the boards. Notice of this meeting is required under the Government through the Sunshine Act (Public Law 94-409) and regulations of the Institute of Museum and Library Services, 45 CFR 1180.84.

**TIME/DATE:** 9-12 p.m. on Friday, November 5, 1999.

**STATUS:** Open.

**ADDRESS:** The Board Room of American Society of Association Executives, 1575 I Street, NW., Washington, DC 20005-1168, (202) 626-2723.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Lyons, Special Assistant to the Director, Institute of Museum and Library Services, 1100 Pennsylvania Avenue, NW, Room 510, Washington, DC 20506, (202) 606-4649.

**SUPPLEMENTARY INFORMATION:** The National Museum Services Board is established under the Museum Services Act, Title II of the Arts, Humanities, and Cultural Affairs Act of 1976, Public Law 94-462. The Board has responsibility for the general policies with respect to the powers, duties, and authorities vested in the Institute under the Museum Services Act.

The United States National Commission on Libraries and Information Science (NCLIS) is established under Public Law 91-345 as amended, The National Commission on Libraries and Information Science Act. In accordance with section 5(b) of the Act, the Commission has the responsibility for advising the Director of the Institute of Museum and Library Services on general policies relating to library services.

The meeting on Friday, November 5, 1999 will be open to the public. If you need special accommodations due to a disability, please contact: Institute of Museum and Library Services, 1100 Pennsylvania Avenue, NW, Washington, DC 20506—(202) 606-8536—TDD (202) 606-8636 at least seven (7) days prior to the meeting date.

**Agenda—3rd Annual Meeting of the National Museum Services Board and the National Commission on Libraries and Information Science at The Board Room of American Society of Association Executives 1575 I Street, NW, Washington, DC 20005-1168 on Friday, November 5, 1999**

9 a.m.-12 p.m.

- I. Chairmen's Welcome
- II. Museums and Libraries and the 21st Century Learner
- III. National Award for Library Service/ National Award for Museum Service
- IV. Digital Library for Education
  - a. White House Initiative
  - b. IMLS Response
- V. National Leadership Grants
  - a. Presentation-RISD
  - b. Panel Observers
  - c. Advisory Committee Reports

d. Discussion  
**VI. Outcomes-based Evaluation: Agency-wide Initiatives**

Dated: October 14, 1999.

**Linda Bell,**

*Director of Policy, Planning and Budget, National Foundation on the Arts and Humanities, Institute of Museum and Library Services.*

[FR Doc. 99-27518 Filed 10-18-99; 1:07 am]

BILLING CODE 7036-01-M

#### **NORTHEAST DAIRY COMPACT COMMISSION**

##### **Notice of Meeting**

**AGENCY:** Northeast Dairy Compact Commission.

**ACTION:** Notice of meeting.

**SUMMARY:** The Compact Commission will hold its monthly meeting to consider matters relating to administration and enforcement of the price regulation, including the reports and recommendations of the Commission's standing Committees. The Commission will also hold its deliberative meeting to consider whether to implement a supply management program. The deliberative meeting was postponed at the September 1, 1999 and October 6, 1999 meetings.

**DATES:** The meeting is scheduled for 10:00 a.m. on Wednesday, November 10, 1999.

**ADDRESSES:** The meeting will be held at The Centennial Inn, Armenia White Room, 96 Pleasant Street, Concord, New Hampshire (I-93 Exit 14).

**FOR FURTHER INFORMATION CONTACT:** Kenneth M. Becker, Executive Director, Northeast Dairy Compact Commission, 34 Barre Street, Suite 2, Montpelier, VT 05602. Telephone (802) 229-1941.

**Authority:** 7 U.S.C. 7256.

Dated: October 14, 1999.

**Kenneth M. Becker,**

*Executive Director.*

[FR Doc. 99-27323 Filed 10-19-99; 8:45 am]

BILLING CODE 1650-01-P

#### **NUCLEAR REGULATORY COMMISSION**

[Docket No. 50-410]

##### **Niagara Mohawk Power Corporation; Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing**

The U.S. Nuclear Regulatory Commission (the Commission or NRC)



is considering issuance of an amendment to Facility Operating License No. NPF-69, issued to the Niagara Mohawk Power Corporation (NMPC or the licensee), for operation of the Nine Mile Point Nuclear Station, Unit No. 2 (NMP2), located in Oswego County, New York.

The proposed amendment, requested by the licensee in a letter dated October 16, 1998, was supplemented by letters dated December 30, 1998, May 10, June 15, July 30, August 2, 11, 16, 19, 27, September 10, and 30, 1999. The application requests a full conversion from the current Technical Specifications (CTS) to a set of improved Technical Specifications (ITS) based on NUREG-1433 and NUREG-1434, "Standard Technical Specifications (STS) for General Electric Plants, BWR/4 and BWR/6," Revision 1, dated April 1995. NUREG-1433 and NUREG-1434 have been developed by the Commission's staff through working groups composed of both NRC staff members and industry representatives, and have been endorsed by the NRC staff as part of an industry-wide initiative to standardize and improve the Technical Specifications (TS) for nuclear power plants. As part of this submittal, the licensee has applied the criteria contained in the Commission's "Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors (Final Policy Statement)," published in the **Federal Register** on July 22, 1993 (58 FR 39132), to the CTS, and, using NUREG-1433 and NUREG-1434 as a basis, proposed an ITS for NMP2. The criteria in the Final Policy Statement were subsequently added to 10 CFR 50.36, "Technical Specifications," in a rule change that was published in the **Federal Register** on July 19, 1995 (60 FR 36953) and became effective on August 18, 1995.

The licensee has categorized the proposed changes to the CTS into four general groupings. These groupings are characterized as administrative changes, relocated changes, more restrictive changes, and less restrictive changes.

Administrative changes are those that involve restructuring, renumbering, rewording, interpretation and complex rearranging of requirements, and other changes not affecting technical content or substantially revising an operating requirement. The reformatting, renumbering and rewording process reflect the attributes of NUREG-1433 and NUREG-1434 and does not involve technical changes to the existing TS. The proposed changes include (a) providing the appropriate numbers, etc., for NUREG-1433 and NUREG-1434

bracketed information (information that must be supplied on a plant-specific basis, and which may change from plant to plant), (b) identifying plant-specific wording for system names, etc., and (c) changing NUREG-1433 and NUREG-1434 section wording to conform to existing licensee practices. Such changes are administrative in nature and do not impact initiators of analyzed events or assumed mitigation of accident or transient events.

Relocated changes are those involving relocation of requirements and surveillances for structures, systems, components, or variables that do not meet the criteria for inclusion in TS. Relocated changes are those current TS requirements that do not satisfy or fall within any of the four criteria specified in 10 CFR 50.36(c)(2)(ii) and may be relocated to appropriate licensee-controlled documents.

The licensee's application of the screening criteria is described in Attachment 1 of the licensee's October 16, 1998, submittal, which is entitled, "Application of Selection Criteria to NMP2 Technical Specifications" (Split Report) in Volume 1 of the submittal. The affected structures, systems, components or variables are not assumed to be initiators of analyzed events and are not assumed to mitigate accident or transient events. The requirements and surveillances for these affected structures, systems, components, or variables will be relocated from the TS to administratively controlled documents such as the quality assurance program, the final safety analysis report (FSAR), the ITS BASES, the Technical Requirements Manual (TRM) that is incorporated by reference in the FSAR, the Core Operating Limits Report (COLR), the Offsite Dose Calculation Manual (ODCM), the Inservice Testing (IST) Program, or other licensee-controlled documents. Changes made to these documents will be made pursuant to 10 CFR 50.59 or other appropriate control mechanisms, and may be made without prior NRC review and approval. In addition, the affected structures, systems, components, or variables are addressed in existing surveillance procedures that are also subject to 10 CFR 50.59. These proposed changes will not impose or eliminate any requirements.

More restrictive changes are those involving more stringent requirements compared to the CTS for operation of the facility. These more stringent requirements do not result in operation that will alter assumptions relative to the mitigation of an accident or transient event. The more restrictive

requirements will not alter the operation of process variables, structures, systems, and components described in the safety analyses. For each requirement in the STS that is more restrictive than the CTS that the licensee proposes to adopt in the ITS, the licensee has provided an explanation as to why it has concluded that adopting the more restrictive requirement is desirable to ensure safe operation of the facility because of specific design features of the plant.

Less restrictive changes are those where CTS requirements are relaxed or eliminated, or new plant operational flexibility is provided. The more significant "less restrictive" requirements are justified on a case-by-case basis. When requirements have been shown to provide little or no safety benefit, their removal from the TS may be appropriate. In most cases, relaxations previously granted to individual plants on a plant-specific basis were the result of (a) generic NRC actions, (b) new NRC staff positions that have evolved from technological advancements and operating experience, or (c) resolution of the Owners Groups' comments on the Improved Standard Technical Specifications (ISTS). Generic relaxations contained in NUREG-1433 and NUREG-1434 were reviewed by the NRC staff and found to be acceptable because they are consistent with current licensing practices and NRC regulations. The licensee's design is being reviewed to determine if the specific design bases and licensing bases are consistent with the technical bases for the model requirements in NUREG-1433 and NUREG-1434, thus providing a basis for these revised TS, or if relaxation of the requirements in the CTS is warranted based on the justification provided by the licensee.

These administrative, relocated, more restrictive, and less restrictive changes to the requirements of the CTS do not result in operations that will alter assumptions relative to mitigation of an analyzed accident or transient event.

In addition to the proposed changes solely involving the conversion, there are also proposed changes that are different from the requirements in both the CTS and the STS (NUREG-1433 and NUREG-1434). These proposed beyond-scope issues to the ITS conversion are as follows:

1. ITS 3.1.8, changing the Scram Discharge Volume Vent and Drain Valve ACTIONS to allow continued operation with one valve in a line inoperable by isolating the penetration within 7 days (ACTION A) and to allow continued operation with two valves in a line by isolating the penetration within 8 hours



(ACTION B). The ISTS requires the valves(s) to be restored to Operable status within 7 days.

2. ITS 3.3.1.1, ITS 3.3.6.1, ITS 3.5.1, and ITS 3.5.2, adding a Note to the Reactor Protection System (RPS) (Functions 3 and 4) and Isolation (Main Steam Line Isolation Valve (MSIV) Functions) Instrumentation Specifications exempting the sensors from response time testing and a Note to the Emergency Core Cooling System (ECCS)—Operating and—Shutdown Specifications exempting the instrumentation from response time testing.

3. ITS 3.3.2.2, allowing the feedwater pump to be removed from service in lieu of shutting down the unit to < 25% Rated Thermal Power (RTP) when the feedwater and main turbine high water level channel is inoperable and untripped.

4. ITS 3.3.3.1, ITS 3.3.3.2, ITS 3.3.8.2, ITS 3.3.8.3 and ITS 3.4.7, adding a Note to allow 6 hours to do Surveillance testing of the Post Accident Monitoring, Remote Shutdown System, RPS logic bus Electrical Power Assemblies (EPAs), RPS scram solenoid bus EPAs and Leak Detection System, instrumentation channels prior to entering Actions.

5. ITS 3.3.4.2, adding an allowance to only remove the associated (Anticipated Transient Without Scram ATWS)—recirculating pump trip (RPT) breaker (fast speed or slow speed, as applicable) from service, in lieu of removing the entire pump from service.

6. ITS 3.3.5.1, ITS 3.3.8.1, ITS 3.3.8.2 and ITS 3.3.8.3, changing the Allowable Values for (a) the Low Pressure Cooling Injection (LPCI) and High Pressure Core Spray (HPCS) minimum flow valves instrumentation; (b) the HPCS suppression pool water level swap over instrumentation; (c) the Loss of Voltage and Degraded Voltage Functions, including time delays; (d) the Undervoltage, Overvoltage, and Underfrequency Functions for the RPS Logic Bus EPAs; and (e) the Undervoltage, Overvoltage, and Underfrequency Functions for the RPS Scram Solenoid Bus EPAs.

7. ITS 3.3.6.1, deleting the MODE 1 and 2 requirements for certain Shutdown Cooling Isolation Functions (residual heat removal (RHR) Equipment Area temperature, Reactor Building Pipe Chase Temperature, Reactor Building Temperature, and Reactor Vessel Water Level—Low, Level 3.)

8. ITS 3.3.8.1 and ITS 3.3.5.1, deleting the Group 4 valves from isolation instrumentation requirements.

9. ITS 3.3.8.1, changing the requirement to only requiring 2

channels of degraded voltage and loss of voltage in lieu of three channels.

10. ITS SR 3.4.1.1 requiring verification every 12 hours that operation is in the “Unrestricted Zone” of ITS Figure 3.4.1–1. This will ensure that entry into a region where potential instabilities can occur will not go undetected.

11. ITS 3.4.1, changing from 2 hours to 8 hours the frequency for determining the Average Power Range Monitors (APRM) and Low Power Range Monitors (LPRM) baseline noise level the first time the unit is in the Restricted Zone.

12. ITS 3.4.5, changing the frequency for monitoring the floor drain leakage rate from 8 hours to 12 hours, and changing the airborne radioactivity monitoring Surveillance to be every 8 hours.

13. ITS 3.5.1, changing the current number of Automatic Depression System (ADS) valves required to operate from seven to six.

14. ITS 3.5.1, modifying the current requirement of manually opening the ADS valves to only require the ADS actuators to be cycled.

15. ITS 3.6.1.3, changing the current requirement that each excess flow check valve (EFCV) must “check flow” to requiring each EFCV to actuate to its isolation position on an actual or simulated instrument line break signal.

16. ITS 3.6.1.3, changing the evolution to suspend the purging and venting Limited Condition Operation (LCO) Actions to within 1 hour, when Standby Gas Treatment (SGT) subsystem(s) are inoperable.

17. ITS 3.6.1.6, ITS 3.6.2.3 and ITS 3.5.2.4, deleting the current requirements to verify position of “automatic” valves in the RHR Drywell Spray, RHR Suppression Cooling, and RHR Suppression Pool Spray Systems.

18. ITS 3.6.1.6 and ITS 3.6.2.4, deleting the current requirement that drywell spray and suppression pool spray flows be through the heat exchanger.

19. ITS 3.7.2 and ITS 3.7.3, allowing a 7-day restoration time when both Control Room Envelope Filtration (CREF) subsystems are inoperable and a 30-day restoration time when both control room envelope alternating current (AC) subsystems are inoperable, provided the remaining components of the CREF System or Control Room Envelope AC System maintains the CREF System or Control Room Envelope AC System safety function, as applicable.

20. ITS 3.8.1, ITS 3.8.2, and ITS 3.8.3, changing AC Sources—Operating, AC Sources—Shutdown and Diesel Fuel Oil, Lube Oil, and Starting Air

Specifications to include: (a) More restrictive upper and lower voltage limits for various diesel generator (DG) Surveillances; (b) increasing the kilowatt (KW) value for the single largest load surveillance requirement (SR) for the Division 3 DG; (c) relaxing the load range values for the 24-hour DG run to be consistent with Regulatory Guide (RG) 1.9 Reference 3 (ISTS Bases says 100% for 22 hours and 110% for 2 hours is consistent with RG 1.9 Reference 3, but it isn't); (d) increasing the DG start time in the event of a Loss of Voltage signal from 13 seconds to 13.12 seconds; (e) adding a Note which exempts Surveillances pertaining to a DG starting on a loss-of-coolant accident (LOCA) signal and a LOCA/loss of offsite power (LOOP) signal while in Modes 4 and 5 and during handling of irradiated fuel in the Secondary Containment when the ECCS subsystems are not required to be Operable; and (f) increasing the fuel oil storage tank limits for the Division 1 and 2 DGs as well as the 6-day limits for all three DGs.

21. ITS 3.8.4, changing the DC Sources—Operating Specification by: (a) revising of the battery load profile to be consistent with the load profile specified in the Updated Safety Analysis Report (USAR); and (b) addition of an allowance to perform a modified performance discharge test every cycle in lieu of a service test.

22. ITS 3.8.7, requiring that the inverters be capable of being powered from an uninterruptible power supply (direct current (DC) sources). Currently, this is not required; this is a more restrictive change.

23. ITS 3.3.8.3, specifying an allowable value in the ITS for the time delay setting of the RPS EPA—solenoid instrumentation.

24. ITS 3.3.8.1, deleting a requirement in the STS for performing a channel check on undervoltage relays; the status of relays are continuously monitored.

25. ITS 3.3.8.2, specifying allowances in allowable values for the time delay settings of the RPS EPA logic instrumentation.

26. ITS 3.3.4.2, adding additional verification of ATWS trip function bypass and time delays.

27. ITS 3.3.8.1, The STS allows a 2-hour delay from entering into the associated Conditions and Required Actions for a channel placed in an inoperable status solely for the performance of required surveillances, provided the associated function maintains DG initiation capability. This is changed in the ITS “provided the Associated Function maintains loss of power (LOP) initiation capability.”

28. ITS 5.5.9.1.a, adding "specific gravity" to the acceptability of new fuel oil prior to the addition to the DG fuel tanks.

29. ITS SR 3.6.3.1.2, adding a description of an additional requirement in the Bases SR 3.6.3.1.2 regarding when to perform the surveillance ("within 30 minutes following heatup of the system to normal operating temperature.")

30. ITS SR 3.3.1.1.16, modifying the Response Time Testing requirement for Function 9, Turbine Control Valve Fast Closure, Trip Oil Pressure—Low by stating that the response time is measured from the start of the control valve fast closure, not when the sensor (oil pressure sensor) exceeds its setpoint.

31. ITS 3.3.5.1, specifying an ADS pressure setpoint of 150 psig, implementing Topical Report NEDC-32291 and making other changes associated with moving Group 4 isolation valves into the ECCS TS in the ITS.

32. ITS 3.3.5.1, Table 3.3.5.1-1, specifying an ADS pressure setpoint for low pressure core spray (LPCS) pump discharge pressure—high to be 150 psig based on implementation of Topical Report NEDC-32291.

33. ITS 3.3.2.1, deleting operational details in CTS Table 3.3.6-2 not required to be in TS, and providing allowable values based on NEDO-2411.

34. ITS 3.3.6.1, deleting the reactor core isolation reactor core isolation cooling (RCIC) drywell pressure high isolation functions, providing new RCIC/RHR Steam Flow Timer and SGT Exhaust Radiation High isolation functional allowable values, and deleting the main steam line (MSL) radiation high isolation function.

35. ITS 3.6.1.2, changing the requirement to verify that the air lock door seal leakage rate is within limit from "once per 7 days" to "once in 30 days."

36. ITS 3.6.1.7, adding a note to allow separate condition entry for each suppression chamber-to-drywell vacuum breaker.

37. ITS 3.6.1.7, changing the ACTION statement into two ACTION statements: ITS 3.6.1.7 ACTION B addresses the closing of the open vacuum breaker within 72 hours, while ITS 3.6.1.7 ACTION C addresses the verification/closing of the other vacuum breaker in the line within 2 hours. However, both ITS 3.6.1.7 Conditions B and C have been modified such that the words "One or more lines with" have been added.

38. ITS 3.4.4, increasing the lift setpoint tolerance for the safety relief valves to 3%.

39. ITS 3.3.1.1, deleting the MSL radiation monitor reactor trip requirement and surveillance requirement based on the application of NEDO-31400A.

40. ITS 3.7.2 SR 3.7.2.1, deleting the staggered testing requirement for the CREF subsystem.

41. ITS 3.3.1.2, adding a note to ITS SR 3.3.1.2.5 that defers determination of the signal-to-noise ratio in Mode 5 if less than or equal to four fuel assemblies are adjacent to the source range monitors (SRM) and no fuel is in the quadrant.

42. ITS 3.3.1.2, changing the STS Action to "initiate action to insert all insertable control rods. \* \* \*" to "Initiate action to "fully" insert all insertable control rods. \* \* \*"

43. ITS 3.3.5.1, ITS Table 3.3.5.1-1, changing footnote (a) from the STS to include a citation of LCO 3.5.2.

44. ITS 5.5.2.b, adding a note that the provisions of SR 3.0.2 apply to integrated leak tests at 24 months.

45. ITS 3.8.8, incorporating changes to Condition A, B and C of the STS applicable to "one or more" Divisions and to "one or both."

46. ITS 3.6.4.1, incorporating wording changes that alter the meaning of containment operability with respect to meeting surveillance requirements.

Before issuance of the proposed license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By November 19, 1999, the licensee may file a request for a hearing with respect to issuance of the amendment to the NMP2 operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and

Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one

contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to Mr. Mark J. Wetterhahn, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(I)-(v) and 2.714(d).

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendment dated October 16, 1998, as supplemented by letters dated December 30, 1998; May 10, June 15, July 30, August 2, 11, 16, 19, 27, September 10, and 30, 1999, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Dated at Rockville, Maryland, this 14th day of October, 1999.

For the Nuclear Regulatory Commission.

**Darl S. Hood, Sr.,**

*Project Manager, Section 1, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 99-27364 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-245, 50-336 and 50-423]

### Northeast Nuclear Energy Company, et al. (Millstone Nuclear Power Station, Unit Nos. 1, 2, and 3); Exemption

#### I

Northeast Nuclear Energy Company, et al. (NNECO or the licensee) is the holder of Facility Operating License Nos. DPR-21, NPF-65, and NPF-49, which authorize operation of the Millstone Nuclear Power Station, Units 1, 2, and 3 (Millstone or the facilities). The facilities consist of two pressurized-water reactors (Units 2 and 3) licensed for operation and one boiling-water reactor (Unit 1) that is being decommissioned, located at the licensee's site in New London County, Connecticut. The licenses provide, among other things, that the licensee is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC or the Commission) now or hereafter in effect.

#### II

Section IV.F.2.c of Appendix E to 10 CFR part 50 requires each licensee at each site to conduct an exercise of offsite emergency plans biennially with full participation by each offsite authority having a role under the plan. During such biennial full-participation exercises, the NRC evaluates onsite and the Federal Emergency Management Agency (FEMA) evaluates offsite emergency preparedness activities. NNECO successfully conducted a full-participation exercise during the week of August 21, 1997. By letter dated August 3, 1999, the licensee requested an exemption from Sections IV.F.2.c of Appendix E regarding the conduct of a full-participation exercise in September 1999. The licensee will conduct the Federally observed full-participation emergency exercise before the end of March 2000 rather than September 1999. Future full-participation exercises will be scheduled biennially from the year 2000. The NRC has provided flexibility in scheduling these exercises by allowing licensees to schedule full-participation exercises at any time during the biennial calendar year. This

provides a 12 to 36 month window to schedule full-participation exercises while still meeting the biennial requirement specified in the regulations. Conducting the Millstone full-participation exercise in calendar year 2000 places the exercise past the previously scheduled biennial calendar year of 1999. This one-time change in the exercise schedule would increase the interval between full-participation exercises in this one instance from the previously scheduled 25 months to 31 months, which is within the time span normally accepted for biennial exercises.

The Commission, pursuant to 10 CFR 50.12(a)(1), may grant exemptions from the requirements of 10 CFR part 50 that are authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security. The Commission, however, pursuant to 10 CFR 50.12(a)(2), will not consider granting an exemption unless special circumstances are present. Under 10 CFR 50.12(a)(2)(ii), special circumstances are present when application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. Under 10 CFR 50.12(a)(2)(v), special circumstances are present whenever the exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation.

#### III

The staff has completed its evaluation of NNECO's request for an exemption and proposed compensatory measures that will be taken to maintain the level of emergency preparedness at Millstone between September 1999 and March 2000. Compensatory measures include the conduct of a self-evaluated drill in September 1999 in accordance with 10 CFR part 50, appendix E, section IV.F.2.b of the onsite emergency plan to which offsite agencies in Connecticut and New York have been invited to participate as a training activity for their responders. Further, the licensee plans an additional drill in October 1999 for State and local responders. The underlying purpose for conducting a biennial full-participation exercise is to ensure that emergency organization personnel are familiar with their duties and to test the adequacy of emergency plans. The intent of this requirement will be met by conducting these two scheduled drills, one of which is specifically for offsite response

organizations. These drills are in excess of what the regulation requires and provide a benefit by allowing more opportunities for training of response personnel. The staff considers that these measures are adequate to maintain an acceptable level of emergency preparedness during this period, satisfying the underlying purpose of the rule. Therefore, the special circumstances of 10 CFR 50.12(a)(2)(ii) are satisfied.

Only temporary relief from the regulation is provided by the requested schedular exemption since an exercise will be conducted at a future date. The licensee has made a good faith effort to comply with the regulation. The exemption is being sought by the licensee in voluntary response to a request by the NRC to accommodate an adjustment in exercise scheduling that affects multiple agencies, as discussed during the annual NRC Region I and FEMA (Regions I, II, and III) exercise scheduling meeting held in White Plains, New York, in December 1998. At this meeting, representatives of the States of Connecticut and New York concurred with rescheduling the NRC/FEMA evaluated exercise for the Millstone site. The revised exercise schedule allows for better balance in the use of federal resources. The exercise will be conducted in a time frame that is within generally accepted policy. In FEMA's letter to the NRC dated July 14, 1999, FEMA Region I and FEMA Headquarters concurred with the change in exercise date. Also, NRC Region I, who would be involved in evaluating the onsite activities during these exercises, supported the schedule change due to the need to relieve resource demands. The staff, having considered the schedule and resource issues within FEMA and the NRC, and the proposed licensee compensatory measures, believes that the exemption request meets the special circumstances of 10 CFR 50.12(a)(2)(v) and should be granted.

#### IV

The Commission has determined that, pursuant to 10 CFR part 50, appendix E, this exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Further, the Commission has determined, pursuant to 10 CFR 50.12(a), that special circumstances of 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(v) are applicable in that application of the regulation is not necessary to achieve the underlying purpose of the rule, and the exemption would provide only temporary relief from the applicable regulation and the

licensee has made good faith efforts to comply with the regulation. Therefore, the Commission hereby grants the exemption from Section IV.F.2.c of Appendix E to 10 CFR part 50.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will have no significant impact on the quality of the human environment (64 FR 50840).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 14th day of October, 1999.

For the Nuclear Regulatory Commission.

**John A. Zwolinski,**

*Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 99-27365 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

### NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-272 and 50-311]

#### Public Service Electric and Gas Company, Salem Nuclear Generating Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. DRP-70 and DRP-75, issued to Public Service Electric and Gas Company (the licensee) for operation of the Salem Nuclear Generating Station, Unit Nos. 1 and 2, located in Salem County, New Jersey.

#### Environmental Assessment

##### Identification of the Proposed Action

The proposed action would make administrative and editorial changes to correct errors in the Technical Specifications (TSs) that have either existed since initial issuance or were introduced during subsequent changes. In addition, surveillance requirements would be added that should have been incorporated within the TSs when the applicable amendment to the TSs was approved by the NRC.

The proposed action is in accordance with the licensee's application for amendment dated November 14, 1997, as supplemented by letter dated August 25, 1999.

##### The Need for the Proposed Action

The proposed action would correct administrative and editorial errors in the TSs. These changes can generally be described as:

a. Revisions to the index to reflect correct page numbers of corresponding sections,

b. Revisions to the section titles used in the TS sections, Bases, and Tables, as well as the correction and addition of subtitles to obtain standardization between both Salem units' TSs,

c. Revision to the TS references that refer to other TS sections and tables to either provide the correct reference or to provide more specificity by reference to actual subsections,

d. Spelling and grammatical corrections such as elimination of duplicate or extraneous words, proper pluralization, more standard abbreviations,

e. Renumbering of TS Tables,

f. Capitalize terms found in TS 1.0 when used in other TS sections,

g. Add units of measure that were missing from acceptance criterion,

h. Other administrative changes.

The proposed action would also revise various surveillance requirements for instrumentation such as including the correct operational mode applicability and adding channel functional tests and channel checks that should have been incorporated when prior amendments were issued.

#### Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that the administrative and editorial changes correct errors that currently exist in the TSs and add surveillance requirements that should have been included in prior amendments. The proposed action does not modify the facility or affect the manner in which the facility is operated. Further, the addition of missing surveillance requirements would better demonstrate the operability of the affected plant components.

The proposed action will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not involve any historic sites. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the Commission concludes that there are no significant environmental impacts associated with the proposed action.

#### *Alternatives to the Proposed Action*

As an alternative to the proposed action, the staff considered denial of the proposed action (i.e., the "no-action" alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

#### *Alternative Use of Resources*

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Salem Nuclear Generating Station dated April 1973.

#### *Agencies and Persons Consulted*

In accordance with its stated policy, on September 14, 1999, the staff consulted with the New Jersey State official, Mr. Dennis Zannoni, Chief of the Bureau of Nuclear Engineering, regarding the environmental impact of the proposed action. The State official had no comments with respect to the environmental impact of the proposed action. However, the State commented that certain proposed corrections were no longer relevant due to previous amendments.

#### **Finding of No Significant Impact**

On the basis of the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated November 14, 1997, as supplemented by letter dated August 25, 1999, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Salem Free Public Library, 112 West Broadway, Salem, NJ 08079.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 14th day of October, 1999.

**Patrick D. Milano, Sr.,**

*Project Manager, Section 2, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 99-27361 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

## **NUCLEAR REGULATORY COMMISSION**

### **Public Workshop On Revising The Reactor Safety Goal Policy**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is considering modifying the reactor Safety Goal Policy Statement that was issued in 1986. Modifications are being considered for three reasons: (1) To change or add to the basic policy established in the statement; (2) to clarify the role of safety goals in the NRC's regulatory process; and (3) to make the policy statement consistent with our current agency practices. NRC is soliciting public comments on modifications that are being considered.

**SUPPLEMENTARY INFORMATION:** NRC's Safety Goal Policy Statement was originally published in 1986 after several years of consideration. The Commission provided additional guidance in a Staff Requirements Memorandum issued June 15, 1990. The current Safety Goal Policy contains two qualitative safety goals defined as follows:

- Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.
- Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks from generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

Two quantitative health objectives (QHOs) associated with the qualitative goals are also provided and are defined as:

- The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.
- The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

In the document SECY-98-101 dated May 4, 1998 (available from the NRC

web site at <http://www.nrc.gov/NRC/COMMISSION/SECYS/1998-101scy>), the staff discussed several issues relevant to changing the Safety Goal Policy Statement. The descriptions of these issues are provided below. The NRC is soliciting feedback regarding these issues, specifically with respect to:

- Should the policy statement be revised to address these issues?
- What are the benefits of such revisions?
- What are the detriments of such revisions?
- What alternatives should be considered to address these issues?

Other specific questions will be made available on the NRC web site at (<http://www.nrc.gov/NRC/wwwforms.html>) two weeks prior to the workshop.

### **Changes or Additions to Basic Policy Established in the Statement**

1. Core damage frequency is now considered a subsidiary objective to the quantitative health objectives (QHOs). It may be appropriate to elevate it to a fundamental safety goal.

2. The second qualitative goal and QHO deal with societal risk. However, these measures of societal risk differ in two key respects from the societal risk calculations performed in other areas:

- The policy statement defines a 10-mile radius for calculating societal impacts, while the Regulatory Analysis Guidelines and environmental impact analyses use a 50 mile radius.
- The calculational process used by the staff for comparison with the QHO is an average-individual risk, while the Regulatory Analysis Guidelines and environmental analyses use a summed risk (over all individuals).

Should the Safety Goal Policy be revised to better reflect societal risk?

3. The goals and QHOs are described in terms of health risks; no goal has been established with respect to potential land contamination or other environmental impacts. As evidenced by the Chernobyl accident, this can be a major societal impact of accidents involving core damage and containment failure. Should such a goal be added?

4. The QHOs are expressed in terms of annual average frequencies. It may be appropriate to also provide a quantitative goal on risks during temporary plant configurations such as during PWR mid-loop operations, where risk can be substantially higher for a short period of time. Should such a goal be included in the Safety Goal Policy Statement?

### **Clarifications on the Role of Safety Goals in NRC's Regulatory Process**

5. In a June 15, 1990, SRM, the Commission provided guidance to the

staff that the safety goals were to be used to define "how safe is safe enough." (In that SRM, the Commission characterized "how safe is safe enough" as "how far [the staff] should go when proposing safety enhancements, including those to be considered under the Backfit Rule.") The policy statement itself does not include this guidance. Should it be added?

6. Recognizing recent progress in risk-informed regulatory activities, should discussion of the relationship between the safety goals and these activities be considered for inclusion in the policy statement?

7. The Advisory Committee on Reactor Safeguards (ACRS) discussed the potential use of safety goals to define the adequate protection concept. Should such a definition be pursued?

8. The policy statement mentions defense-in-depth but does not define it. Should the policy be expanded to provide more guidance on the extent and nature of defense-in-depth?

#### Changes To Make the Statement Consistent With Current Practices

9. Two issues were identified in the staff's recent risk-informed regulatory guidance development activities, and discussed as policy issues in SECY-96-218, dated October 11, 1996, and SECY-97-287, dated December 12, 1997:

- Plant-specific application of safety goals, including a containment performance guideline derived from the QHOs (and defined in terms of a large early release frequency (LERF)).
- Treatment of uncertainties in plant-specific, risk-informed decisionmaking. It may be appropriate to discuss the resolution of these issues in the Safety Goal Policy Statement.

10. The current policy statement contains a proposed general plant performance guideline of  $10^{-6}$  per reactor year for a large release of radioactive material. In SECY-93-138 the staff documented its conclusion that such a guideline would be significantly more restrictive than the QHOs. The staff further recommended that work to develop such a guideline be terminated. The Commission approved this recommendation in a June 10, 1993, SRM. Therefore, removal of this general plant performance guideline from the policy statement should be considered.

#### Workshop Meeting Information

The Commission intends to conduct a workshop to solicit information related to the revising the reactor safety goal. Persons other than NRC staff and NRC contractors interested in making a presentation at the workshop should notify Joseph Murphy, Office of Nuclear

Regulatory Research, MS-T10 F12, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, (301-415-5670), email: jam1@nrc.gov

Date: November 9, 1999.

Agenda: Preliminary agenda is as follows (a final agenda will be available at the workshop):

9:00 a.m. Introduction  
 9:30-10:15 Overview of issues  
 10:15-10:30 Break  
 10:30-12:00 Discussion of specific questions  
 12:00-1:00 Lunch break  
 1:00-2:30 Discussion of specific questions (continued)  
 2:30-2:45 Break  
 2:45-4:00 Discussion of specific questions (continued)  
 4:00-5:00 Wrap-up discussion  
 Location: Doubletree Hotel, 1750 Rockville Pike, Rockville Maryland 20852, (301-468-1100).

Registration: No registration fee for workshop; however, notification of attendance is requested so that adequate space, etc., for the workshop can be arranged. Notification of attendance should be directed to Joseph Murphy, Office of Nuclear Regulatory Research, MS: T10-F12, U. S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, (301) 415-5670, email: jam1@nrc.gov

#### FOR FURTHER INFORMATION CONTACT:

Joseph Murphy, Office of Nuclear Regulatory Research, MS: T10 F12, U. S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, (301) 415-5670, email: jam1@nrc.gov

Dated this 14th day of October 1999.

For the Nuclear Regulatory Commission.

Thomas L. King,

Director, Division of Risk Analysis and Applications, Office of Nuclear Regulatory Research.

[FR Doc. 99-27363 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

#### NUCLEAR REGULATORY COMMISSION

##### NRC To Hold Public Meetings on Spent Fuel Shipping Cask Accident Studies

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of public meeting on spent nuclear fuel transportation studies.

SUMMARY: The U.S. Nuclear Regulatory Commission is initiating a study on spent nuclear fuel cask responses to severe transportation accidents. NRC previously studied this issue in the 1980s (see NUREG/CR-4829 and NUREG/BR-0111, called the "modal

study"). The modal study looked at possible rail and highway accidents and concluded that spent nuclear fuel cask designs would survive nearly all transportation accidents without releasing radioactive material to the environment. Over the next few years NRC will revisit the conclusions of the 1987 modal study to assure their continued validity. Risk insights obtained using modern analysis techniques, physical testing, and through interaction with stakeholders and the public, will support NRC's ongoing efforts to assure that its regulatory actions are risk-informed and effective. Ongoing public interactions throughout this project will help ensure that public concerns are effectively identified and understood, and that the project is designed considering these issues.

As the first step, NRC will conduct public meetings with the general public with the goal of having open, constructive discussions by stakeholders so that the NRC can listen to and better understand any public concerns regarding spent nuclear fuel transport package safety. Francis X. Cameron, Special Counsel for Public Liaison, in the Commission's Office of the General Counsel, will be the convenor and facilitator for the meetings.

DATES: Two public meetings will be held. The first will be held in Bethesda, MD, on November 17, 1999, from 8:00 a.m. to 6:00 p.m. The second will be held in Henderson, NV, on December 8, 1999, from 8:00 a.m. to 4:30 p.m. with an evening session from 6:30 p.m. to 10:00 p.m.

ADDRESSES: The location of the first meeting is the Bethesda Hyatt Hotel, One Bethesda Metro (7400 Wisconsin Avenue), Bethesda, MD. The second meeting will be held at the Henderson Convention Center, 200 Water Street, Henderson, NV.

INFORMATION: Contact Francis X. Cameron, Special Counsel for Public Liaison, Office of the General Counsel, Nuclear Regulatory Commission, Washington DC, 20555-0001, Telephone: 301-415-1642.

SUPPLEMENTARY INFORMATION: The risk of transporting highly radioactive spent nuclear fuel from nuclear power plants to a centralized storage facility or to an underground repository is an issue that has recently received increased NRC and public attention because of the increase in the number of shipments that will occur if and when such facilities begin operating. Risk to the public from transportation accidents depends on accident rates, number of

shipments, and the likely consequences and severity of the accidents. About 1300 shipments of spent nuclear fuel have been made in NRC-certified packages, with an exceptional safety record of no releases from accidents. Despite the previous studies and safety record, some stakeholders may have questions or concerns regarding spent nuclear fuel transport package safety. Several groups have criticized NRC's cask standards and the modal study as being insufficient to adequately demonstrate safety during severe transportation accidents.

The objective of the public meetings is to bring together representatives of the interests affected by the study to discuss their views on the issues in a "roundtable" format. In order to have a manageable discussion, the number of participants around the table will, of necessity, be limited. The Commission, through the facilitator for the meeting, will attempt to ensure participation by the broad spectrum of interests at the meetings, including citizen and environmental groups, nuclear industry interests, state, tribal, and local governments, experts from academia, or other agencies. Other members of the public are welcome to attend, and the public will have the opportunity to comment on each of the agenda items slated for discussion by the roundtable participants. Questions about participation may be directed to the facilitator, Francis X. Cameron.

The meetings will have a pre-defined scope and agenda focused on the major technical issues in regard to spent nuclear fuel cask performance during transportation accidents. However, the meeting format will be sufficiently flexible to allow for the introduction of additional related issues that the participants may wish to raise. The purpose of the meetings is to hear the views of the participants on the issues and options to resolve the issues for the forthcoming study. The agenda for the meetings is set forth below.

#### Agenda

Introductions and Welcome  
 E. William Brach, Director, Spent Fuel Project Office, NRC  
 Susan F. Shankman, Deputy Director, Spent Fuel Project Office, NRC  
 Ground Rules, Agenda Overview, Introduction of Participants  
 Francis X. Cameron, Facilitator  
 Overview of NRC Studies on Transportation Risk  
 NRC Staff  
 NRC Plans for the Modal Study Update  
 Robert Lewis, NRC  
 General Overview of the Study Updates  
 Sandia National Laboratories

#### Discussion of Issues

##### Participants and Audience Summary and Closing Remarks

Dated at Rockville, Maryland, this 14th day of October, 1999.

For the Nuclear Regulatory Commission.

**Susan F. Shankman,**

*Deputy Director, Licensing and Inspection Directorate, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 99-27362 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

#### NUCLEAR REGULATORY COMMISSION

##### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Nuclear Regulatory Commission.

**DATE:** Weeks of October 18, 25, November 1, and 8, 1999.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

##### MATTERS TO BE CONSIDERED:

###### *Week of October 18*

Wednesday, October 20

9:25 a.m. Affirmation Session (Public meeting) (if needed)

9:30 a.m. Meeting with Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD) (Public meeting) (Contact: Paul Lohaus, 301-415-3340)

Thursday, October 21

9:30 a.m. Briefing on Part 35—Rule on Medical Use of Byproduct Material (Public Meeting) (Contact: Cathy Haney, 301-415-6825) (SECY-99-201, *Draft Final Rule—10 CFR Part 35, Medical Use of Byproduct Material*, is available in the NRC Public Document Room or on NRC web site at: "www.nrc.gov/NRC/COMMISSION/SECYS/index.html" Download the *zipped version* to obtain all attachments.)

###### *Week of October 25—Tentative*

There are no meetings scheduled for the Week of October 25.

###### *Week of November 1—Tentative*

Thursday, November 4

9:25 a.m. Affirmation Session (Public Meeting) (if needed)

9:30 a.m. Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: John Larkins, 301-415-7360)

#### *Week of November 8—Tentative*

Tuesday, November 9

9:00 a.m. Meeting on NRC Interactions with Stakeholders on Nuclear Materials and Waste Activities (Public Meeting)

Wednesday, November 10

9:25 a.m. Affirmation Session (Public Meeting) (if needed)

9:30 a.m. Briefing on Draft Maintenance Regulatory Guide (Public Meeting) (Contact: Richard Correia, 301-415-1009)

\*The schedule for commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415-1292. Contact person for more information: Bill Hill (301) 415-1661.

\* \* \* \* \*

The NRC Commission Meeting Schedule can be found on the Internet at:

<http://www.nrc.gov/SECY/smj/schedule.htm>

\* \* \* \* \*

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, DC 20555 (301-415-1661). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to [wmh@nrc.gov](mailto:wmh@nrc.gov) or [dkw@nrc.gov](mailto:dkw@nrc.gov).

Dated: October 15, 1999.

**William M. Hill, Jr.,**

*SECY Tracking Officer, Office of the Secretary.*

[FR Doc. 99-27459 Filed 10-18-99; 10:46 am]

BILLING CODE 7590-01-M

#### NUCLEAR REGULATORY COMMISSION

##### **Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations**

##### **I. Background**

Pursuant to Public Law 97-415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section



189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from September 25, 1999, through October 7, 1999. The last biweekly notice was published on October 6, 1999 (64 FR 54370).

**Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing**

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission

expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administration Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By November 19, 1999, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in

the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment



and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

*Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona*

*Date of amendments request:*  
September 14, 1999

*Description of amendments request:*  
Request No. 1: The proposed administrative change to Technical Specification (TS) 5.5.2, Primary Coolant Sources Outside Containment, would delete the references to the post-accident sampling return piping of the radioactive waste gas system and the post-accident sampling return piping of the liquid radwaste system because the Palo Verde post-accident sampling system does not have return lines to the radioactive waste gas or liquid radwaste systems.

Request No. 2: This proposed TS amendment would also delete the administrative requirement in TS 5.6.2,

Annual Radiological Environmental Operating Report, that states: "[t]he report shall identify the TLD [thermoluminescence dosimeter] results that represent collocated dosimeters in relation to the NRC TLD program and the exposure period associated with each result."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

*Request No. 1*

Standard 1—Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No—This proposed administrative change to Technical Specification (TS) 5.5.2 to delete references to the radioactive waste gas system and liquid radwaste system in the context of the post accident sampling system (PASS) does not involve a significant increase in the probability or consequences of an accident previously evaluated. Leak testing requirements of the PASS return piping are included in the TS 5.5.2 requirements that are not being changed. The appropriate PASS piping, including return piping, is leak tested per the prescribed requirements in TS 5.5.2. This administrative change would simply clarify TS 5.5.2, since the PASS return piping is not part of the waste gas or liquid radwaste systems. There is no physical connection between the PASS piping and the radioactive waste gas or liquid radwaste systems. The radioactive waste gas system and the liquid radwaste system are not part of PASS and would not contain highly radioactive fluids during a serious transient or accident to be subject to TS 5.5.2. This administrative change would involve no change to the design or maintenance of the plant and no changes in the functional requirements of any system.

Standard 2—Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No—This proposed administrative change to delete references to the radioactive waste gas system and liquid radwaste system in the context of PASS does not create the possibility of a new or different kind of accident from any accident previously evaluated. Leak testing requirements of the PASS return piping are implicitly included in the TS 5.5.2 requirements that are not being changed. The appropriate PASS piping, including return piping, is leak tested per the prescribed requirements in TS 5.5.2. There is no physical connection between the PASS piping and the radioactive waste gas or liquid radwaste systems. The radioactive waste gas system and the liquid radwaste system are not part of PASS and would not contain highly radioactive fluids during a serious transient or accident to be subject to TS 5.5.2. This administrative change would involve no change to the design or maintenance of the

plant and no changes in the functional requirements of any system. This administrative change would simply clarify TS 5.5.2, since the PASS return piping is not part of the waste gas or liquid radwaste systems.

Standard 3—Does the proposed change involve a significant reduction in a margin of safety?

No—This proposed administrative change does not involve a significant reduction in a margin of safety. There is no margin of safety associated with this proposed administrative change to Technical Specification 5.5.2. Leak testing requirements of the PASS return piping are implicitly included in the TS 5.5.2 requirements that are not being changed. The appropriate PASS piping, including return piping, is leak tested per the prescribed requirements in TS 5.5.2. This administrative change would involve no change to the design or maintenance of the plant and no changes in the functional requirements of any system. This administrative change would simply clarify TS 5.5.2, since the PASS return piping is not part of the waste gas or liquid radwaste systems.

*Request No. 2*

Standard 1—Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No—This proposed administrative change to Technical Specification (TS) 5.6.2 does not involve a significant increase in the probability or consequences of an accident previously evaluated. This proposed TS amendment would delete the administrative requirement in TS 5.6.2, Annual Radiological Environmental Operating Report, that states: "[t]he report shall identify the TLD results that represent collocated dosimeters in relation to the NRC TLD program and the exposure period associated with each result." The NRC ended their TLD program at the end of 1997. The requirements of TS 5.6.2 and the changes being made with this request are purely administrative reporting requirements that have no effect on the design, operation, or maintenance of the plant. Since there is no effect on the design, operation, or maintenance of the plant, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Standard 2—Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No—This proposed administrative change to TS 5.6.2 does not create the possibility of a new or different kind of accident from any accident previously evaluated. This change only affects administrative reporting requirement and has no effect on the design, operation, or maintenance of the plant. Since this proposed change is purely administrative and would have no effect on the design, operation, or maintenance of the plant, this change will not create possibility of a new or different type of accident than any previously evaluated.

Standard 3—Does the proposed change involve a significant reduction in a margin of safety?

No—This proposed administrative change to TS 5.6.2 does not involve a significant reduction in a margin of safety. This TS establishes requirements for reporting radiological monitoring information to the NRC. Since TS 5.6.2 contains an administrative reporting requirement, and this proposed change would simply delete an administrative requirement associated with a discontinued NRC monitoring program, there is no margin of safety associated [with] this TS or with the proposed changes to the requirements of TS 5.6.2. Also, since this involves only administrative reporting, this change has no [e]ffect on any other margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on that review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

*Local Public Document Room*

*location:* Phoenix Public Library, 1221 N. Central Avenue, Phoenix, Arizona 85004

*Attorney for licensee:* Nancy C. Loftin, Esq., Corporate Secretary and Counsel, Arizona Public Service Company, P.O. Box 53999, Mail Station 9068, Phoenix, Arizona 85072-3999

*NRC Section Chief:* Stephen Dembek

*CBS Corporation (Licensee),  
Westinghouse Test Reactor, Waltz Mill Site, Westmoreland, Pennsylvania,  
Docket No. 50-22, License No. TR-2*

*Date of amendment request:*  
September 7, 1999, as supplemented on October 1, 1999

*Description of amendment request:*  
CBS Corporation is the licensee for the Westinghouse Test Reactor (WTR) at Waltz Mill, Pennsylvania. The licensee is authorized to only possess the reactor and a decommissioning plan has been approved. The licensee is planning to revise the decommissioning plan by reassigning the responsibilities of the Site Manager, who works for the Westinghouse Electric Company (a contractor to CBS) to the TR-2 Decommissioning Project Director who works for CBS.

*Basis for proposed no significant hazards consideration determination:*  
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed amendment to a license of a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed

amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in the margin of safety.

The staff agrees with the licensee's no significant hazards consideration determination submitted on September 7, 1999, for the following reason:

In order to complete the decommissioning of the WTR facility as described in the Decommissioning Plan, CBS has established contractual agreements with the Westinghouse Electric Company to supply continued site support and services to the Westinghouse Test Reactor Facility. CBS has also entered into contracts with other third party organizations as described in the Decommissioning Plan. These contracts will remain in place between CBS and each respective third party so that there will be no effective change in the personnel associated with the on-going decommissioning project under the TR-2 License. CBS continues to retain full responsibility for the project.

The only change being made is that the responsibilities of the Westinghouse Electric Company Site Manager, as it pertains to the WTR and the TR-2 License, has been assigned to the TR-2 Decommissioning Project Director, who works for CBS. The Westinghouse Electric Company personnel who reported to the Site Manager will now report directly to CBS through the contract.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendment does not modify the WTR facility configuration or licensed activities. Thus no new accident initiators are introduced. Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated, and does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Duke Energy Corporation, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina*

*Date of amendment request:*  
September 16, 1999.

*Description of amendment request:*  
The amendments would revise Surveillance Requirements (SRs) 3.8.4.8 and 3.8.4.9 of the Technical Specifications and Bases SR 3.8.4.8 to allow testing of the direct current (DC) channel batteries with the units on line. The proposed change to SR 3.8.4.8 would also prohibit the diesel generator (DG) batteries from being service tested while the units are on line.

*Basis for proposed no significant hazards consideration determination:*  
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

*First Standard*

Implementation of this amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated. Approval of this amendment will have no significant effect on accident probabilities or consequences. The 125 Volt DC Vital Instrumentation and Control Power System is not an accident initiating system; therefore, there will be no impact on any accident probabilities by the approval of this amendment. The design of the system is not being modified by this proposed amendment. It has been shown that the required battery testing can be performed safely with the unit on line well within the allowed outage time for an inoperable DC channel. Both safety trains would continue to be capable of performing their required design functions in the event of an accident. Therefore, there will be no impact on any accident consequences.

*Second Standard*

Implementation of this amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated. No new accident causal mechanisms are created as a result of NRC approval of this amendment request. No changes are being made to the plant which will introduce any new accident causal mechanisms. This amendment request does not impact any plant systems that are accident initiators.

*Third Standard*

Implementation of this amendment would not involve a significant reduction in a margin of safety. Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident situation. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The performance of these fission product barriers will not be impacted by implementation of this proposed

amendment. It has already been shown that both safety trains of the 125 Volt DC Vital Instrumentation and Control Power System will continue to be able to perform their accident mitigation functions should they be required. In addition, the probabilistic risk analysis conducted for this proposed amendment demonstrated that there is no appreciable increase in overall plant risk incurred by its implementation. No safety margins will be impacted.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* York County Library, 138 East Black Street, Rock Hill, South Carolina.

*Attorney for licensee:* Ms. Lisa F. Vaughn, Legal Department (PB05E), Duke Energy Corporation, 422 South Church Street, Charlotte, North Carolina.

*NRC Section Chief:* Richard L. Emch, Jr.

*Energy Northwest, Docket No. 50-397, WNP-2, Benton County, Washington*

*Date of amendment request:* July 29, 1999, as supplemented by letter dated August 30, 1999.

*Description of amendment request:* The proposed amendment would delete a license condition that required installation of a neutron flux monitoring system, in the form of excore wide range monitors (WRM), in conformance with Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident." WNP-2 installed the WRM system in the spring of 1989. Removal of the license condition would allow WNP-2 to deactivate the WRM system. *Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The probability of an evaluated accident is derived from the probabilities of the individual precursors to that accident. The consequences of an evaluated accident are determined by the operability of plant systems designed to mitigate those consequences. As stated in the NRC safety evaluation approving NEDO-31558-A (Reference 2) [in licensee's August 30, 1999

letter], Category 1 neutron flux monitoring instrumentation is not needed for existing BWRs to cope with Loss-of-Coolant Accident (LOCA), Anticipated Transient Without SCRAM (ATWS), or other accidents that do not result in severe core damage conditions. Instrumentation to monitor the progression of core melt accidents would best be addressed by the current severe accident management program. Also, WRM is not included in the WNP-2 IPE/PSA models and WRM is not relied upon for operator actions in the Emergency Operating Procedures (EOPs) or actions accounted for in Severe Accident Management. Therefore, no individual precursors of an accident are affected and the elimination of the WRM does not impact or change the probabilities of accidents previously evaluated. In addition, since the operability of plant systems designed to mitigate accident consequence has not changed, the consequences of an accident previously evaluated are not expected to increase.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Creation of the possibility of a new or different kind of accident would require the creation of one or more new precursors of that accident. New accident precursors may be created by modifications of the plant configuration, including changes in procedures that may create the potential for new or different personnel errors. The elimination of the WRM system does not create the possibility of a new or different kind of accident because plant crews are trained to use the Neutron Monitoring System (NMS) in normal evolutions and under emergency conditions according to EOP guidance. In addition, NEDO-31558-A concludes that the failure of all neutron flux monitoring instrumentation does not prevent the operator from determining the shutdown condition of the reactor. Sufficient information is available on which to base operational decisions and to conclude that reactivity control has been accomplished. For example, Rod Position Information System (RPIS) is powered from an uninterruptible source and remains available even during Station Blackout (SBO) conditions to provide full core control rod position information as a backup reactor power indicator based on calculations of rod worth and shutdown margin. The proposed change does not introduce any new modes of operation or alter system setpoints which could create a new or different kind of accident. Therefore, no new precursors of an accident and no new or different kinds of accidents are created.

3. The proposed change does not involve a significant reduction in a margin of safety.

The elimination of the WRM system does not result in a reduction of the margin of safety. The neutron power indications necessary for operator response to ATWS are provided by the NMS not WRM. Based on a WNP-2 specific evaluation against the alternate criteria specified in NEDO-31558-A, there is sufficient confidence that the instrumentation would still be available to confirm that the reactor is shutdown. In addition, failure of the existing neutron flux

monitoring instrumentation does not prevent plant operators from determining the shutdown condition of the reactor. Sufficient information is available to the operator to make operational decisions and to conclude that reactivity control has been accomplished. The proposed changes will not impact the basis for any Technical Specification related to the establishment or maintenance of nuclear safety margins. Therefore, operation of the facility in accordance with the proposed amendment does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

*Attorney for licensee:* Perry D. Robinson, Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502.

*NRC Section Chief:* Stephen Dembek.

*Florida Power Corporation, et al., Docket No. 50-302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida*

*Date of application for amendment:* February 19, 1999.

*Description of amendment request:* The proposed amendment would revise the Crystal River Unit 3 Improved Technical Specifications Sections 5.6.2.7, 5.6.2.8, and 5.7.2.b, related to the Containment Tendon Surveillance Program. The proposed changes are a result of revisions to 10 CFR 50.55a which are required to be fully implemented by September 9, 2001. These revised requirements affect the surveillance methods for the containment tendons and the conduct of containment visual inspections, and the methods of reporting the results of the required inspections to the NRC.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below.

1. Involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed change to the Crystal River Unit 3 (CR-3) Improved Technical Specifications (ITS) replaces the previous programmatic commitment to implement a Containment Tendon Surveillance Program based on Regulatory Guide 1.35, Revision 3,

with a Containment Inspection Program that complies with the current requirements of 10 CFR 50.55a. Effective September 9, 1996, 10 CFR 50.55a requires licensees to implement a Containment Inspection Program in compliance with the 1992 Edition with the 1992 Addenda of Subsection IWE, "Requirements for Class MC and Metallic Liners of Class CC Components of Light-Water Cooled Power Plants," and with Subsection IWL, "Requirements for Class CC Concrete Components of Light-Water Cooled Power Plants," of Section XI, Division 1, of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code) with additional modifications and limitations as stated in 10 CFR 50.55a(b)(2)(ix). Florida Power Corporation (FPC) is implementing a Containment Inspection Program to comply with these new regulatory requirements. The final rule specifies requirements to assure that the critical areas of the containment structure are routinely inspected to detect and take corrective action for defects that could compromise structural integrity. This proposed ITS change is requested to update the ITS to these latest 10 CFR 50.55a regulatory requirements.

By complying with the regulatory requirements described in 10 CFR 50.55a, the probability of a loss of containment structural integrity is maintained as low as reasonably achievable. Maintaining containment structural integrity is independent of the operation of the reactor coolant system (RCS), and independent of the reactor protection system (RPS) and emergency core cooling system (ECCS). The Containment Inspection Program ensures that the containment will function as designed to provide an acceptable barrier to release of radioactive materials to the environment. By assuring the effectiveness of this barrier through appropriate inspection, and by implementing corrective actions for any degradation discovered during these inspections that might lead to containment structural failures, the probability or consequences of accidents will not be greater than that previously evaluated.

2. Create the possibility of a new or different kind of accident from previously evaluated accidents?

No. Maintaining containment structural integrity is independent of the operation of the RCS, and independent of the RPS and ECCS. By implementing corrective actions for any degradation discovered during the required inspections of the containment, the possibility of a new or different kind of accident will not be created.

3. Involve a significant reduction in a margin of safety?

No. The margin of safety as defined by the CR-3 ITS has not been reduced. By complying with the regulatory requirements described in 10 CFR 50.55a, the probability of a loss of containment structural integrity is maintained as low as reasonably achievable. The Containment Inspection Program ensures that the containment will function as designed to provide an acceptable barrier to release of radioactive materials to the environment. By implementing the Containment Inspection Program, the existing margin of safety is preserved.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* Coastal Region Library, 8619 W. Crystal Street, Crystal River, Florida 34428.

*Attorney for licensee:* R. Alexander Glenn, General Counsel (MAC-BT15A), Florida Power Corporation, P. O. Box 14042, St. Petersburg, Florida 33733-4042.

*NRC Section Chief:* Sheri R. Peterson.

*GPU Nuclear, Inc. et al., Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey*

*Date of amendment request:* July 7, 1999.

*Description of amendment request:* The proposed amendment would revise the Technical Specifications (TSs) to change the component surveillance frequencies for the following TSs to indicate a frequency of once per 3 months: Core Spray System TS 4.4.A.1 and 4.4.A.2, Containment Cooling System TS 4.4.C.1, Emergency Service Water System TS 4.4.D.1, Fire Protection System TS 4.4.F (isolation valves only), and Pressure Suppression Chamber—Drywell Vacuum Breakers TS 4.5.F.5.a. The TSs currently stipulate a component surveillance frequency of once per month. Also, the amendment would revise TS pages 4.4-1 and 4.4-2 to incorporate editorial format changes and TS page 4.4-3 to accommodate the expanded text.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed surveillance interval change does not alter the actual surveillance requirements, nor does it alter the limits and restrictions on plant operations. The reliability of systems and components relied upon to prevent or mitigate the consequences of accidents previously evaluated is not degraded by the proposed change to the surveillance interval. Assurance of system and equipment availability is maintained. The proposed change does not alter any system or equipment configuration.

Based on the above, the proposed change does not significantly increase the probability or consequences of an accident previously evaluated.

2. The proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed surveillance interval change does not alter the actual surveillance requirements, nor does it alter the limits and restrictions on plant operations. Assurance of system and equipment availability is maintained. The proposed change does not alter any system or equipment configuration nor does it introduce any new mechanisms which could contribute to the creation of a new or different kind of accident than previously evaluated.

3. The proposed TS changes do not involve a significant reduction in a margin of safety.

The proposed change extends the surveillance interval for verifying the operability of the specified pumps and valves from once per month to once per three months. The proposed change does not alter the actual surveillance requirements, the limits and restriction on plant operations nor the design, function or manner of operation of any structures, systems or components. System availability and reliability are maintained. Accordingly, the proposed TS change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* Ocean County Library, Reference Department, 101 Washington Street, Toms River, NJ 08753.

*Attorney for licensee:* Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

*NRC Section Chief:* S. Singh Bajwa.

*Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Units 1 and 2, Berrien County, Michigan*

*Date of amendment requests:* September 17, 1999.

*Description of amendment requests:* The proposed amendments would allow credit in the applicable subcriticality analysis for the negative reactivity provided by insertion of the rod cluster control assemblies (RCCAs) during realignment from a cold leg recirculation to a hot leg recirculation configuration. This realignment, which is referred to as hot leg switchover, is performed following a loss-of-coolant accident. This methodology change, when evaluated in accordance with 10 CFR 59.59, resulted in an unreviewed safety question that will require prior approval by the NRC staff in accordance with the provisions of 10 CFR 50.90

prior to implementation. The proposed change would also affect the Bases for Technical Specification (T/S) 3/4.5.5, "Refueling Water Storage Tank," and several sections of the Updated Final Safety Analysis Report (UFSAR).

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated?

No. I&M [Indiana Michigan Power Company] proposes to credit RCCA insertion of negative reactivity for criticality control during the core cooling flow path realignment from cold leg recirculation to hot leg recirculation following the postulated cold leg LBLOCA [large-break loss-of-coolant accident]. No physical modifications will be made to plant systems, structures, or components.

Credit for RCCAs is only being applied to demonstrate core subcriticality upon hot leg switchover (HLSO) following a cold leg LBLOCA. The performance criteria codified in 10 CFR 50.46 continue to be met. The ability of the RCCAs to insert under LOCA and seismic conditions was a function important to safety as part of the original CNP [Cook Nuclear Plant] design basis. This is supported by the conclusion presented in NRC (at the time, the Atomic Energy Commission) Safety Evaluation Report (SER), Section 3.3, "Mechanical Design of Reactor Internals," dated January 14, 1969. The SER includes the statements that, "[t]he control rod guide tubes are designed so that each finger of each control rod assembly is always partially inserted in the guide tube. Deflection limits on the guide tubes have been chosen so that deflections caused by blow-down forces during a loss-of-coolant accident will not prevent control rod insertion," and that the "mechanical design of internals, fuel assemblies, and control elements is acceptable." However, the licensing basis safety analyses for the LBLOCA scenario have conservatively not taken credit for insertion of the RCCAs.

No physical modifications will be made to plant systems, structures, or components in order to implement the proposed methodology change. The safety functions of the safety related systems and components, which are related to accident mitigation, have not been altered. Therefore, the reliability of RCCA insertion is not affected. As such, taking credit for RCCA insertion does not alter the probability of an LBLOCA (the design basis accident at issue). The Westinghouse analyses provided as Attachments 6 and 7 [to the licensee's application] demonstrate that RCCA insertion will occur, with substantial margin, following a design basis cold leg LBLOCA combined with a seismic event. Crediting RCCA insertion does not affect mechanisms for a malfunction that could impact the

HLSO subcriticality analysis, or mechanisms that could initiate a LOCA. Taking credit for the negative reactivity available from insertion of the RCCAs, which is currently assumed for various accident analyses within the CNP licensing basis (e.g., small break LOCA, main steamline break, feedline break, steam generator tube rupture), does not affect equipment malfunction probability directly or indirectly. Therefore, crediting the RCCAs as a source of negative reactivity for post-LOCA criticality control at the time of HLSO does not significantly increase the probability of an accident previously evaluated.

Furthermore, the traditional conservative assumption that the most reactive RCCA is stuck fully out of the core is being maintained. A malfunction that results in one RCCA to fail to insert is a credible scenario, and is being considered for the post-LOCA subcriticality analysis following a cold leg LBLOCA. There will be sufficient negative reactivity, even with the most reactive RCCA stuck fully out of the core, to assure core subcriticality post-LOCA, as supported by the subcriticality analysis that is confirmed each and every fuel cycle as part of the reload documentation (i.e., the Reload Safety Evaluations). The core is shown to remain subcritical during the post-LOCA long-term cooling period, specifically while HLSO is performed. Thus, no additional radiological source terms are generated, and the consequences of an accident previously evaluated in the UFSAR will not be significantly increased.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed change involves crediting the negative reactivity that is available from the RCCAs for an analysis applicable several hours after the initiation of a cold leg LBLOCA. As such, this change involves post-LOCA recovery actions several hours after the break has occurred and does not involve accident initiation. As discussed above, the original design requirements for the CNP reactor internals, core fuel assemblies, and RCCAs were based upon assuring the ability of the RCCAs to insert following a double-ended rupture LOCA with seismic loadings. Thus, the safety functions of safety related systems and components have not been altered by this change. Crediting the negative reactivity that is available from the RCCAs for the post-LOCA subcriticality analysis upon HLSO does not cause the initiation of any accident, nor does the proposed activity create any new credible limiting single failure. Crediting the insertion of RCCAs does not result in any event previously deemed incredible being made credible nor is there any introduction of any new failure mechanisms that are not currently considered in the design basis LOCA. There are no changes introduced by this amendment concerning how safety related equipment is designed to operate under normal or design basis accident conditions since the calculations supporting RCCA insertion following a cold leg LBLOCA have assumed design basis break sizes in conjunction with seismic loadings. Therefore, the possibility of an accident of a different type than already evaluated in the UFSAR is not created.

3. Does the change involve a significant reduction in a margin of safety?

No. Presently, no credit is taken for RCCA insertion in the analysis to demonstrate post-cold leg LOCA subcriticality at the time of HLSO. The current subcriticality analysis for this scenario relies only on the boron provided by the RWST [refueling water storage tank] and the accumulators. Thus, RCCA insertion provides another source of negative reactivity (margin of safety). Revising the post-cold leg LBLOCA HLSO subcriticality analysis to credit the negative reactivity associated with the RCCAs is a means to offset the sump dilution associated with the effects of the inactive regions of the CNP containment sump. The incorporation of this "defense-in-depth" source of negative reactivity in the HLSO subcriticality analysis has been conservatively determined to cause a reduction in the margin of safety. 10 CFR 50, Appendix K, I.A.2., states, in part, that "[r]od trip and insertion may be assumed if they are calculated to occur," and provides for crediting RCCA insertion as an acceptable feature of emergency core cooling system (ECCS) evaluation models. The proposed change is based upon an analysis for CNP that demonstrates that the control rods will indeed insert and the resulting negative reactivity can be credited for post-LOCA criticality control.

The proposed change would ensure that post-LOCA subcriticality is maintained during HLSO. Subsequently, there would not be a challenge to long-term core cooling due to a return to a critical condition. This being the case, the requirements of 10 CFR 50.46(b)(5) that, "the calculated core temperature shall be maintained at an acceptably low value and decay heat shall be removed for the extended period of time" continues to be satisfied and the margin of safety in the CNP licensing basis is preserved. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

**Local Public Document Room location:** Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, MI 49085.

**Attorney for licensee:** Jeremy J. Euto, Esq., 500 Circle Drive, Buchanan, MI 49107.

**NRC Section Chief:** Claudia M. Craig.

**Power Authority of the State of New York, Docket No. 50-333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York**

**Date of amendment request:** September 29, 1999.

**Description of amendment request:** The proposed amendment requests a Technical Specification change that

would extend the allowed out-of-service time for the residual heat removal service water system (RHRSW) from 7 days to 11 days on a one-time basis while modifications are made on the RHRSW "A" strainer.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Operation of the FitzPatrick plant in accordance with the proposed amendment would not involve a significant hazards consideration as defined in 10 CFR 50.92 since it would not:

Involve an increase in the probability or consequences of an accident previously evaluated.

The Conditional Core Damage Probability due to this proposed change is calculated to be 6.4 E-8. This value falls below the threshold probability of 1 E-6 for risk significance of temporary changes to the plant configuration in the EPRI PSA [Electric Power Research Institute Probability Assessment] Applications Guide (Reference 3) [see application dated September 29, 1999].

This proposed change does not increase the consequences of an accident previously evaluated because all relevant accidents (LOCA) [loss-of-coolant accident] would result in the transfer of decay heat to the suppression pool. For this scenario, the same complement of equipment will be available to achieve and maintain cold shutdown as is required by the current Technical Specification LCO [limiting condition for operation].

Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change does not physically alter the plant. As such, no new or different types of equipment will be installed. The new design for the RHRSW strainer packing gland will be evaluated under a separate 10 CFR 50.59 evaluation and is considered to be functionally equivalent for the purposes of this one-time-only proposed Technical Specification change.

The implementation and use of the contingency plan for achieving limited containment heat removal in the event the B division of RHRSW is rendered inoperable will be evaluated under the Authority's 10 CFR 50.59 program.

Involve a significant reduction in a margin of safety.

The Conditional Core Damage Probability due to this proposed change is calculated to be 6.4 E-8. This value falls below the threshold probability of 1 E-6 for risk significance of temporary changes to the plant configuration in the EPRI PSA Applications Guide (Reference 3).

The consequences of a postulated accident occurring during the extended allowable out-service time are bounded by existing analyses therefore there is no significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

**Attorney for licensee:** Mr. David E. Blabey, 1633 Broadway, New York, New York 10019.

**NRC Section Chief:** S. Singh Bajwa.

**Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama**

**Date of amendment request:** December 1, 1998, as supplemented by letters of April 21, 1999, and July 19, 1999.

**Description of amendment request:** The proposed amendments would revise the Technical Specifications to reflect replacing the current Model 51 steam generators with Westinghouse Model 54F steam generators. The replacement program includes re-analyzing and evaluating loss-of-coolant-accident (LOCA) and non-LOCA mass and energy releases, containment and sub-compartment pressure and temperature responses, dose analyses, and the effects on nuclear steam supply and balance of plant systems.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not significantly increase the probability or consequences of an accident previously evaluated in the [Final Safety Analysis Report] FSAR. The comprehensive engineering effort performed to support [steam generator] SG replacement has included evaluations or re-analysis of all accident analyses including all dose related events. All dose consequences have been analyzed or evaluated with respect to these proposed changes, and all acceptance criteria continue to be met. Therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident than any accident already evaluated in the FSAR. No new accident scenarios, failure mechanisms or limiting single failures are introduced as a result of the proposed changes. The proposed technical specification changes have no adverse effects

on any safety-related system and do not challenge the performance or integrity of any safety-related system. Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed technical specification changes do not involve a significant reduction in a margin of safety. All applicable analyses supporting the [steam generator] SG replacement reflect these proposed values. All acceptance criteria (including LOCA peak clad temperature, [departure from nucleate boiling] DNB, containment temperature and pressure, and dose limits) continue to be met. Therefore, the proposed changes do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed Southern Nuclear Company's analysis, and based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** Houston-Love Memorial Library, 212 W. Burdeshaw Street, Post Office Box 1369, Dothan, Alabama 36302.

**Attorney for licensee:** M. Stanford Blanton, Esq., Balch and Bingham, Post Office Box 306, 1710 Sixth Avenue North, Birmingham, Alabama.

**NRC Section Chief:** Richard L. Emch, Jr.

**Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, (SQN), Units 1 and 2, Hamilton County, Tennessee**

**Date of application for amendments:** June 30, 1999 (TS 98-10).

**Description of amendment requests:** The proposed amendments would change the Sequoyah (SQN) Operating Licenses DPR-77 (Unit 1) and DPR-79 (Unit 2) by updating the current Technical Specification requirements for reactor coolant system leakage detection and operational leakage specifications.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), has provided its analysis of the issue of no significant hazards consideration, which is presented below:

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed revisions enhance the Technical specification (TS) requirements to provide greater consistency with the standard TS in NUREG-1431. This revision proposes changes to the requirements for reactor coolant system (RCS) leak detection and RCS operational leakage in Specifications 3.4.6.1 and 3.4.6.2, respectively. New Specifications



3.4.6.3 and 3.5.6 for RCS pressure isolation valves and emergency core cooling system (ECCS) seal injection flow have been added to improve consistency with NUREG-1431. The proposed revisions are not the result of changes to plant equipment, system design, testing methods, or operating practices. The modified requirements will allow some relaxation of current operability criteria, action requirements, and surveillance requirements (SRs). These changes provide more appropriate requirements in consideration of the safety significance and the design capabilities of the plant as determined by the improved standard TS industry effort. These specifications serve to primarily provide identification and control of the RCS fission product barrier leakage and ECCS degradation and are not considered to be a contributor to the generation of postulated accidents. Since these proposed revisions will continue to support the required safety functions, without modification of the plant features, the probability of an accident is not increased.

The proposed changes will allow relaxation of action times for inoperable leak detection features and the components that can be inoperable. The required actions to ensure acceptable pressure isolation valve capability with an inoperable valve have been revised to allow isolation by a single valve for a limited period of time. These revisions will allow unit operation for a longer period of time with reduced system redundancy. However, the redundancy reduction and action time increases are not significant and will continue to provide an acceptable level of safety considering the significance of RCS leakage, other design features or compensatory actions that provide equivalent functions, and the unlikely chance of an event that would require functions for leakage identification during the proposed time interval. These considerations are consistent with the basis developed by the industry and NRC for NUREG-1431. Surveillances have been removed from the RCS operational leakage specification as a result of relocated requirements, duplication of other SRs, and testing requirements that do not provide a significant benefit in the identification of RCS leakage. The SRs that have been retained or relocated to other TS specifications will provide acceptable verifications for the timely identification of conditions that indicate an unacceptable amount of RCS leakage or potential ECCS degradation resulting from excessive seal injection flow.

The limiting condition for operation associated with the seal injection flow requirements has been revised to utilize a modified operability criteria. The proposed change will provide a range of differential pressures and the corresponding seal flows that would be representative of the existing single point flow limit. This change does not alter the intent of the operability requirements, but does allow the flexibility to use equivalent values that provide the same level of assurance for ECCS operability. The proposed operability condition for seal injection flow enhances the current requirement by establishing additional test

parameters that will ensure that the amount of seal injection flow does not degrade the ECCS functions.

The proposed changes to the SQN TS provide flexibility without modifying the functions of required safety systems. In many instances the proposed changes ensure that plant conditions for surveillance testing are more appropriate for testing purposes and the verification of system operability.

These changes are consistent with the intent of NUREG-1431 and result in the enhancement of the SQN TSs based on the latest industry and NRC positions. The provisions proposed in this change request will continue to maintain an acceptable level of protection for the health and safety of the public and will not significantly impact the potential for the offsite release of radioactive products. The overall effect of the proposed change will result in specifications that have equivalent or improved requirements compared to existing specifications for RCS leakage and ECCS operability and will not significantly increase the consequences of an accident.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed revisions are not the result of changes to plant equipment, system design, testing methods, or operating practices. The modified requirements will allow some relaxation of current operability criteria, action requirements, and SRs consistent with NUREG-1431. These changes provide more appropriate requirements in consideration of the safety significance and the design capabilities of the plant as determined by the improved standard TS industry effort. These specifications serve to primarily provide identification and control of the RCS fission product barrier leakage and ECCS degradation and are not considered to be a contributor to the generation of postulated accidents. Since the functions of the associated systems will continue to perform without change and were not previously considered to contribute to accident generation, the proposed changes will not create the possibility of a new or different kind of accident.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

The proposed changes, associated with RCS leakage and ECCS functions, will not result in changes to system design or setpoints that are intended to ensure timely identification of plant conditions that could be precursors to accidents or potential degradation of accident mitigation systems. These systems will continue to operate without change and only the associated actions or testing activities have been altered. Revisions to the actions and surveillances provide some relaxation and flexibility such that longer intervals are allowed for inoperable components and testing requirements are revised to provide conditions that provide more accurate results. The increased action times are acceptable considering the available redundant features, the compensatory measures provided by the actions, and the

allowed time intervals that have been developed by the industry and NRC and recommended in NUREG-1431. The SR changes actually provide test condition requirements that enhance the accuracy of the activity even though they may allow a delay in the performance of the test. These surveillance changes are also in accordance with NUREG-1431 recommendations.

These revisions will continue to provide the necessary actions to minimize the impact of inoperable equipment to an acceptable level and will provide testing activities that will ensure system operability. Since the setpoints and design features that support the margin of safety are unchanged and actions for inoperable systems continue to provide appropriate time limits and compensatory measures, the proposed changes will not significantly reduce the margin of safety.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 10H, Knoxville, Tennessee 37902.

*NRC Section Chief:* Sheri R. Peterson.

*Tennessee Valley Authority, Docket No. 50-390 Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee*

*Date of amendment request:* September 28, 1999 (TS 99-007).

*Description of amendment request:* The proposed amendment on Response Time Test (RTT) elimination would revise the Watts Bar Nuclear Plant Unit 1 Technical Specifications (TS) definitions for "Engineered Safety Feature (ESF) Response Time" and "Reactor Trip System (RTS) Response Time" to provide for verification of response time for selected components provided that the components and the methodology for verification have been previously reviewed and approved by the NRC. In addition, associated changes to the Bases for Surveillance Requirements would also be made.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

This change to the TS does not result in a condition where the design, material, and



construction standards that were applicable prior to the change are altered. The same RTS and ESF instrumentation is being used, the time response allocations/modeling assumptions in the Chapter 15 analyses are unchanged; only the method of verifying time response is changed. The proposed change will not modify any system interface and could not increase the likelihood of an accident since these events are independent of this change. The proposed activity will not change, degrade or prevent actions, or alter any assumptions previously made in evaluating the radiological consequences of an accident described in the UFSAR [Updated Final Safety Analysis Report]. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

This change does not alter the performance of pressure and differential pressure transmitters, process protection racks (Eagle 21), nuclear instrumentation (NIS), and logic system (SSPS) used in the plant protection systems. These components/systems will still have response time verified by test prior to placing the equipment in operational service and after any maintenance that could affect the response time of that equipment. Changing the method of periodically verifying instrument response time for applicable instrumentation from RTT to calibration and channel checks or functional test will not create any new accident initiators or scenarios. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

This change does not affect the total system response time assumed in the safety analysis. The periodic system response time verification method for selected pressure and pressure differential sensors, Eagle 21, NIS, and SSPS is modified to allow use of actual test data or engineering data. The method of verification still provides assurance that the total system response time is within that assumed in the safety analysis, since calibration checks and functional tests will detect any degradation which might significantly affect equipment response time. Therefore, the proposed license amendment request does not result in a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room location:* Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, TN 37402.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 10H, Knoxville, Tennessee 37902.

*NRC Section Chief:* Sheri Peterson.

*Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont*

*Date of amendment request:* June 15, 1999.

*Description of amendment request:* The licensee proposed revisions to Technical Specifications (TSs) Sections 3.1/4.1 Reactor Protection System and 3.2/4.2 Protective Instrument Systems instrumentation, tables, and the associated bases to increase the surveillance test intervals (STIs), add allowable out-of-service times (AOTs), replace generic ECCS actions for inoperable instrument channels with function-specific actions, and relocate selected trip functions from the TSs to a Vermont Yankee (VY) controlled document. In addition, revision to TS Section 3.1/4.1 Reactor Protection System and the associated bases is proposed to remove the RUN Mode APRM Downscale/IRM High Flux/Inoperative Scram Trip Function (APRM Downscale RUN Mode SCRAM). The submittal also proposes to implement editorial corrections and administrative changes that do not alter the meaning or intent of the requirements.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. The operation of Vermont Yankee Nuclear Power Station in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

VY has determined that the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated. The generic analysis contained in Licensing Topical Report NEDC-30851P-A assessed the impact of changing SCRAM (RPS) surveillance test intervals for Logic and Functional tests (STIs) and adding allowable out-of-service times (AOTs) on the SCRAM (RPS) failure frequency, the scram frequency and equipment cycling. Specifically, Section 5.7.4, "Significant Hazards Assessment," of NEDC-30851P-A states that:

"Fewer challenges to the safeguards system, due to less frequent testing of the RPS, conservatively results in a decrease of approximately one percent in core damage frequency. This decrease is based upon the following:

Based on the plant-specific experience presented in Appendix J, the estimated reduction in scram frequency (0.3 scrams/yr.) represents a 1 to 2 percent decrease in core damage frequency based on the BWR plant-specific Probabilistic Risk Assessments (PRAS) listed in Table 5-8.

The increase in core damage frequency due to less frequent testing is less than one percent. This increase is even lower (less than 0.01 percent) when the changes resulting from the implementation of the Anticipated Transients Without Scram (ATWS) rule are considered. Therefore, this increase is more than offset by the decrease in CDF due to fewer scrams.

The effect of reducing unnecessary cycles on RPS equipment, although not easily quantifiable, also results in a decrease in core damage frequency.

The overall impact on core damage frequency of the changes in allowable out-of-service times is negligible."

From this generic analysis, the BWR Owners' Group concluded that the proposed changes do not significantly increase the probability or consequences of an accident previously evaluated, namely the increase in probability of a scram failure due to SCRAM (RPS) unavailability is insignificant, and the overall probability of an accident is actually decreased as the time the SCRAM (RPS) Instrumentation logic operates as designed is increased resulting in less inadvertent scrams during testing and repair. Furthermore, the plant specific reports demonstrate[] that although VY differs from the generic model analyzed in License Topical Report NEDC-30851P-A, the net effect of the plant-specific differences do not alter the generic conclusions.

The generic analysis contained in Licensing Topical Reports NEDC-30851P-A Suppl 2/NEDC-31677P-A assessed the impact of changing STIs and AOTs for BWR Isolation Instrumentation common/not common to SCRAM (RPS) and ECCS instrumentation. Specifically, Section 4.0, "Summary of Results," of NEDC-30851P-A Suppl 2 states that:

"The results indicate that the effects on probability of failure to initiate isolation are very small and the effects on probability or frequency of failure to isolate are negligible in nearly every case. In addition, the results indicate that increasing the AOT to 24 hours for tests and repairs has a negligible effect on the probability of failure of the isolation function. These combined with changes to the testing intervals and allowed out-of-service times for RPS and ECCS instrumentation provide a net improvement to plant safety and operations." and Section 5.6, "Assessment of Net Effect of Changes," of NEDC-31677P-A states that:

"A reduction in core damage frequency (CDF) of at least as much as estimated in the ECCS instrumentation analysis can be expected when the isolation actuation instrumentation STIs are changed from one month to three months. The chief contributor to this reduction is the channel functional tests for the MSIVs. Inadvertent closure of the MSIVs will cause an unnecessary plant scram. This reduction in CDF more than compensates for any small incremental

increase (10% or  $10E-07$ /year) in calculated isolation function failure frequency when the STI is extended to three months."

From this generic analysis, the BWR Owners' Group concluded that the proposed changes do not significantly increase the consequences of an accident previously evaluated, namely the increase in probability of an isolation failure due to isolation instrumentation unavailability is insignificant, and the overall probability of an accident is actually decreased as the time the SCRAM (RPS) Instrumentation logic operates as designed is increased resulting in less inadvertent scrams during testing and repair.

The generic analysis contained in Licensing Topical Report NEDC-30936P-A (Parts 1 and 2) assessed the impact of changing STIs and AOTs for all BWR ECCS Actuation Instrumentation. Specifically, Section 4.0, "Technical Assessment of Changes," of NEDC-30936P-A (Part 2) states that:

"The results indicate an insignificant (less than  $5E-7$  per year) increase in water injection function failure frequency when STIs are increased from 31 days to 92 days, AOTs for repair of the ECCS actuation instrumentation are increased from one hour to 24 hours, and AOTs for surveillance testing are increased from two to six hours. For all four BWR models the increase represents less than 4% increase in failure frequency. However, when other factors which influence the overall plant safety are considered, the net result is judged to be an improvement in plant safety."

From this generic analysis, the BWR Owners' Group concluded that the proposed changes do not significantly increase the probability or consequences of an accident previously evaluated, namely the increase in probability of a water injection failure due to ECCS instrumentation unavailability is insignificant and the net result is judged to be an improvement in plant safety. Furthermore, the plant specific report demonstrates that although VY differs from the generic model analyzed in Licensing Topical Report NEDC30936P-A, the net affect of the plant-specific differences do not alter the generic conclusions.

The generic analysis contained in Licensing Topical Report NEDC-30851 P-A Supp 1, assessed the impact of changing Rod Block STIs on Rod Block failure frequency. Specifically, Section 5 (BNL's Tech. Eval. Report—Attach. 2 to the NRC SER) of NEDC-30851 P-A Suppl 1 states that:

"The BWR Owners' Group proposed changes to the Technical Specifications concerning the test requirements for BWR control rod block instrumentation. The changes consist of increasing the surveillance test intervals from one to three months. These test interval extensions are consistent with the already approved changes to STIs for the reactor protection system. The technical analysis reviewed and verified as documented herein indicates that there will be no significant changes in the availability of the control rod block function if these changes are implemented. In addition, there will be a negligible impact on the plant core melt frequency due to the decreased testing."

From this generic analysis, the BWR Owners' Group concluded that the proposed changes do not significantly increase the probability of an accident previously evaluated or consequences of an accident previously evaluated.

Bases contained in GE Topical Report GENE-770-06-1 assessed the impact of changing STIs and AOTs on selected systems failure frequency. Specifically, Section 2.0, "Summary," of GENE 770-06-1 states that: "Technical bases are provided for selected proposed changes to the instrumentation STIs and AOTs that were identified in the BWROG Improved BWR Technical Specification activity. These STI and AOT changes are consistent with approved changes to the RPS, ECCS, and isolation actuation instrumentation. These proposed changes do not result in a degradation to overall plant safety."

From these Bases, the BWR Owners' Group concluded that the proposed changes do not significantly increase the probability of an accident previously evaluated or consequences of an accident previously evaluated.

Bases contained in GE Topical Report GENE-770-06-2 assessed the impact of changing STIs and AOTs on selected systems (RCIC Actuation) failure frequency. Specifically, Section 2.0, "Summary," of GENE 770-06-2 states that:

"The STI and AOT changes to the RCIC actuation instrumentation are justified based on their small effect on the water injection function unavailability and consistency with comparable changes to the actuation instrumentation for the other ECCS subsystems". These STI and AOT changes are consistent with approved changes to the RPS, ECCS, and isolation actuation instrumentation. These proposed changes do not result in a degradation to overall plant safety."

From these Bases, the BWR Owners' Group concluded that the proposed changes do not significantly increase the probability of an accident previously evaluated or consequences of an accident previously evaluated.

The proposed change will not alter the physical characteristics of any plant systems or components and all safety-related systems and components remain within their applicable design limits. Thus, system and component performance is not adversely affected by this change, thereby assuring that the design capabilities of those systems and components are not challenged in a manner not previously assessed so as to create the possibility of a new or different kind of accident.

The addition of allowable out-of-service times (AOTs) and the increase in surveillance test intervals (STIs) does not alter the function of the SCRAM (RPS), ECCS, Isolation, Rod Block, and Selected Instrument Systems nor involve any type of plant modification and no new modes of plant operation are involved with these changes.

No physical change is being made to any systems or components that are credited in the safety analysis, therefore there is no change in the probability or consequences of any accident analyzed in the UFSAR.

The design basis accident applicable to the startup power region is the Control Rod Drop Accident (CRDA). The UFSAR does not credit the RUN Mode IRM High Flux/Inoperative with the associated APRM downscale scram Trip Function (APRM downscale RUN Mode SCRAM) in the termination of this accident. Accident mitigation is provided by the APRM 120% power scram. Therefore, elimination of the APRM downscale RUN Mode SCRAM function has no adverse affect on previously evaluated accidents.

The Continuous Control Rod Withdrawal Error (CWE) transient is terminated by the Rod Block Monitor (RBM) in the RUN Mode. The APRM Reduced High Flux Scram provides the primary STARTUP Mode protection in conjunction with the IRMs and limits the consequences of this transient. Therefore, elimination of the APRM downscale RUN Mode SCRAM function has no effect on the consequences of this transient.

Adding a new surveillance to verify SRM/IRM/APRM will enhance neutron monitoring during startups and shutdowns and does not have an adverse affect on previously evaluated accidents.

None of the proposed changes will affect any of the rod blocks or other precursor events to either the CRDA or CWE. Therefore, there is no change in the probability of any accident previously analyzed.

Use of ECCS Function-specific AOTs, actions and relocation of Bus Power Monitors to a licensee controlled document is consistent with STS and does not have an adverse affect on previously evaluated accidents.

In addition, VY concluded the editorial corrections and administrative changes do not involve a significant increase in the probability or consequences of an accident previously evaluated. These changes do not alter the meaning or intent of any requirements.

2. The operation of Vermont Yankee Nuclear Power Station in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from an accident previously evaluated.

VY has determined that the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change will not alter the physical characteristics of any plant systems or components and all safety-related systems and components remain within their applicable design limits. Thus, system and component performance is not adversely affected by this change, thereby assuring that the design capabilities of those systems and components are not challenged in a manner not previously assessed so as to create the possibility of a new or different kind of accident. Editorial corrections and administrative changes do not alter the meaning or intent of any requirements.

The addition of allowable out-of-service times (AOTs), ECCS function-specific actions and the increase in surveillance test intervals (STIs) does not alter the function of the SCRAM (RPS), ECCS, Isolation, Rod Block,

and Selected Instrument Systems nor involve any type of plan modification and no new modes of plant operation are involved with these changes. Therefore, operation in accordance with the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Elimination of APRM downscale RUN Mode SCRAM function affects only the operations of neutron monitoring and protective systems (IRM and APRM) which provide indication and mitigation actions only. Operation of these systems does not create the possibility for new precursors (such as reactivity) which would introduce a new or different kind of accident from any accident previously evaluated.

Additionally, the proposed changes do not affect the ability of those systems required to mitigate previously evaluated accidents during the modes they are credited.

3. The operation of Vermont Yankee Nuclear Power Station in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety. The NRC staff has reviewed and approved the generic studies contained in the GE Topical Reports (LTRs) and has concurred with the BWR Owners' Group that the proposed changes do not significantly affect the availability of the SCRAM (RPS), ECCS, Isolation, Rod Block, or Selected Instrument Systems. The proposed addition of allowable out-of-service times (AOTs) for the instruments addressed in the LTRs provide reasonable time for making repairs and performing tests. The lack of sufficient AOTs in the current Technical Specifications (TS) creates a hurried atmosphere during repairs and tests that could cause an increased risk of error. In addition, placing an individual channel in a tripped condition because no AOT exists, as in the current TS, increases the potential of an inadvertent scram. The proposed AOTs provide realistic times to complete the required actions without increasing the overall instrument failure frequency. Use of ECCS Function-specific AOTs, actions and relocation of Bus Power Monitors to a licensee controlled document is consistent with STS and there is no significant reduction in the margin of safety.

Editorial corrections and administrative changes do not alter the meaning or intent of any requirements. Therefore, there is no significant reduction in the margin of safety.

The incorporation of extended surveillance test intervals (STIs) does not result in significant changes in the probability of instrument failure, as demonstrated by the LTRs. In addition, the TS calibration frequency has not changed, and therefore assurance exists that the setpoints will not be affected by drift.

These changes, when coupled with the reduced probability of test-induced plant transients and equipment failures, result in an overall increase in the margin of safety.

The only scram function that the UFSAR takes credit for in the mitigation of the limiting accident (control rod drop accident) is the APRM 120% power scram which is not affected by this change. Only the APRM Downscale RUN Mode SCRAM, for which the UFSAR takes no credit in the termination

of any analyzed event, is removed by this change. Removal of the APRM Downscale RUN Mode SCRAM will avoid the need to operate the plant in a "half scram" condition with the potential for an inadvertent plant transient. For these reasons, the change does not involve a significant reduction in a margin of safety.

The Continuous Control Rod Withdrawal Error (CWE) transient is terminated by the Rod Block Monitor (RBM) in the RUN Mode. When initiated from the STARTUP Mode, the consequences of a CWE are limited by the APRM Reduced High Flux scram in conjunction with the IRM scram function. Therefore eliminating the TS requirement for the APRM Downscale RUN Mode SCRAM will not reduce the margin of safety for this transient.

Adding a new surveillance to verify SRM/IRM/APRM overlap will enhance neutron monitoring during startups and shutdown, and consequently does not involve a significant reduction in a margin of safety.

On the basis of the above, VY has determined that operation of the facility in accordance with the proposed change does not involve a significant hazards consideration as defined in 10 CFR 50.92(c), in that it: (1) does not involve a significant increase in the probability or consequences of an accident previously evaluated; (2) does not create the possibility of a new or different kind of accident from any accident previously evaluated; and (3) does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301

**Attorney for licensee:** Mr. David R. Lewis, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037-1128.

**NRC Section Chief:** James W. Clifford.

**Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont**

**Date of amendment request:** September 21, 1999.

**Description of amendment request:** The proposed amendment would modify Technical Specification (TS) 3.10.C, "Diesel Fuel" by increasing the minimum usable volume of diesel fuel in the diesel fuel oil storage tank (FOST). The specified minimum amount of diesel fuel is that quantity necessary to support diesel generator operation for a period of 7 days.

**Basis for proposed no significant hazards consideration determination:**

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Will the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

The diesel generators are used to support mitigation of the consequences of an accident; however, they are not considered the initiator of any previously analyzed accident. This change does not challenge or degrade the performance of any safety system assumed to function in the accident analysis. Since this change simply increases the minimum volume of stored diesel generator fuel in the FOST, its impact is to enhance the long-term operation of diesel generators used to mitigate the consequences of accidents.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Will the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

This change does not affect the design or mode of operation of any plant system, structure or component. No physical alteration of plant structures, systems or components is involved, and no new or different type of equipment will be installed. Thus, no new condition of operation is created. The change is conservative in that it results in a net increase in the minimum required diesel fuel oil stored in the FOST.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated for Vermont Yankee.

3. Will the proposed changes involve a significant reduction in a margin of safety?

The [ ] proposed change does not adversely affect a margin of safety because increasing the minimum required volume of fuel oil provides additional assurance of diesel generator availability and, therefore, maintains or increases the availability of the onsite power supply. Since this change simply increases the quantity of diesel fuel oil available for diesel generator operation, there is no reduction in any value, condition, or range of parameters used in any accident analysis.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** Brooks Memorial Library, 224 Main Street, Brattleboro, VT.

**Attorney for licensee:** Mr. David R. Lewis, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037-1128.

*NRC Section Chief:* James W. Clifford.

*Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas*

*Date of amendment request:*  
September 21, 1999.

*Description of amendment request:*  
The proposed amendment would extend the effective full implementation date by six months, from December 31, 1999, to June 30, 2000, for Amendment 120 issued March 22, 1999. Amendment 120 approved a modification to the plant to increase the storage capacity of the spent fuel pool and increase the nominal fuel enrichment to 5 weight percent U-235. The extension is due to delays fabricating and installing the new spent fuel storage racks.

*Basis for proposed no significant hazards consideration determination:*  
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change is administrative in nature and does not significantly affect any system that is a contributor to initiating events for previously evaluated accidents. The proposed change does not significantly affect any system that is used to mitigate any previously evaluated accidents. Therefore, the proposed change does not involve any significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change is administrative in nature and does not alter the design, function, or operation of any plant component and does not install any new or different equipment. Therefore, a possibility of a new or different kind of accident from those previously analyzed has not been created.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change is administrative in nature and does not involve a significant reduction in the margin of safety associated with the fuel cladding, reactor coolant boundary, containment, or any safety limit.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Local Public Document Room locations:* Emporia State University,

William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621.

*Attorney for licensee:* Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, D.C. 20037.

*NRC Section Chief:* Stephen Dembek.

**Previously Published Notices of Consideration of Issuance of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing**

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

*Consolidated Edison Company of New York, Docket No. 50-003, Indian Point Nuclear Generating Station, Unit No. 1, Buchanan, New York*

*Date of amendment request:* July 20, 1999.

*Description of amendment request:*  
The amendment would revise the Technical Specifications to change the senior reactor license requirement for the Operations Manager.

*Date of publication of individual notice in Federal Register:* September 9, 1999 (64 FR 49027).

*Expiration date of individual notice:* October 12, 1999.

*Local Public Document Room location:* White Plains Public Library, 100 Martine Avenue, White Plains, New York.

*Detroit Edison Company, Docket No. 50-341, Fermi 2, Monroe County, Michigan*

*Date of amendment request:*  
September 24, 1999.

*Description of amendment request:*  
The proposed amendment would revise current Technical Specification (TS) 3.6.1.8 by adding footnote “\*\*\*” to Action b. The footnote would allow continued operation of Fermi 2 with the leakage of penetration X-26 exceeding the limit in TS 4.6.1.8.2, provided certain compensatory measures are

taken. Operation would be allowed to continue until the next plant shutdown.

Because the NRC staff issued the Fermi 2 improved standard TSs (ITS) on September 30, 1999, with implementation within 90 days, the licensee also provided a version of the TS amendment that would be compatible with the ITS. This version would add a new special operations TS, ITS 3.10.8, to address the compensatory actions and other requirements associated with penetration X-26.

*Date of publication of individual notice in Federal Register:* October 1, 1999 (64 FR 53421).

*Expiration date of individual notice:*  
Comment period expires October 15, 1999; Opportunity for hearing period expires November 1, 1999.

*Local Public Document Room location:* Monroe County Library System, Ellis Reference and Information Center, 3700 South Custer Road, Monroe, Michigan 48161.

**Notice of Issuance of Amendments to Facility Operating Licenses**

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety

Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document rooms for the particular facilities involved.

*Commonwealth Edison Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois*

*Date of application for amendments:* May 20, 1999, as supplemented by letters dated September 8, 1999, September 16, 1999, and September 20, 1999.

*Brief description of amendments:* The amendments revised Technical Specification (TS) Section 3.8.A, "Containment Cooling Service Water System," (CCSW) to clarify that only one pump is required to support operability of the Control Room Emergency Ventilation System (CREVS).

*Date of issuance:* October 1, 1999.

*Effective date:* Immediately, to be implemented within 30 days.

*Amendment Nos.:* 174 and 170.

*Facility Operating License Nos. DPR-19 and DPR-25:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 25, 1999 (64 FR 46426). The September 8, September 16, and September 20, 1999, submittals provided additional clarifying information that did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Morris Area Public Library District, 604 Liberty Street, Morris, Illinois 60450.

*Commonwealth Edison Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois*

*Date of application for amendments:* June 15, 1999.

*Brief description of amendments:* The amendments revised Technical Specification (TS) 4.7.D.6 by replacing the leakage limit of 11.5 standard cubic feet per hour (scfh) for each main steam isolation valve (MSIV) with a limit of 46 scfh on the total combined leakage for the MSIVs of all four main steam lines.

*Date of issuance:* October 1, 1999.

*Effective date:* Immediately, to be implemented within 30 days.

*Amendment Nos.:* 175 and 171.

*Facility Operating License Nos. DPR-19 and DPR-25:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* July 14, 1999 (64 FR 38024).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Morris Area Public Library District, 604 Liberty Street, Morris, Illinois 60450.

*Commonwealth Edison Company, Docket Nos. 50-373 and 50-374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois*

*Date of application for amendments:* May 19, 1999.

*Brief description of amendments:* The amendments relocated Technical Specification 3/4.4.4, "Chemistry," from the TS to the Updated Final Safety Analysis Report (UFSAR) and to an Administrative Technical Requirement that has been incorporated into the UFSAR by reference.

*Date of issuance:* October 1, 1999.

*Effective date:* Immediately, to be implemented within 30 days.

*Amendment Nos.:* 134 and 119.

*Facility Operating License Nos. NPF-11 and NPF-18:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* July 14, 1999 (64 FR 38024).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Jacobs Memorial Library, 815 North Orlando Smith Avenue, Illinois Valley Community College, Oglesby, Illinois 61348-9692.

*Duke Energy Corporation, Docket Nos. 50-269, 50-270, and 50-287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina*

*Date of application for amendments:* May 11, 1999, as supplemented by letter dated July 13, 1999.

*Brief description of amendments:* The amendments revised the Technical Specifications by incorporating changes to the pressure-temperature limits; the heatup, cooldown, and inservice test limits for the reactor coolant system to a maximum of 33 Effective Full Power Years; the low temperature overpressure protection system; and operational requirements for the reactor coolant pumps.

*Date of Issuance:* October 1, 1999.

*Effective date:* As of the date of issuance and shall be implemented

within 90 days from the date of issuance.

*Amendment Nos.:* Unit 1-307; Unit 2-307; Unit 3-307.

*Facility Operating License Nos. DPR-38, DPR-47, and DPR-55:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* June 16, 1999 (64 FR 32289).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

*Energy Northwest, Docket No. 50-397, WNP-2, Benton County, Washington*

*Date of application for amendment:* April 7, 1999, as supplemented by letters dated May 25, June 21, August 2, and August 30, 1999.

*Brief description of amendment:* The amendment revises the minimum critical power ratio safety limits.

*Date of issuance:* September 27, 1999.

*Effective date:* September 27, 1999.

*Amendment No.:* 158.

*Facility Operating License No. NPF-21:* The amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* May 19, 1999 (64 FR 27329).

The May 25, June 21, August 2 and August 30, 1999, supplemental letters provided additional clarifying information that did not expand the scope of the application as originally noticed and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 27, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

*Energy Northwest, Docket No. 50-397, WNP-2, Benton County, Washington*

*Date of application for amendment:* April 20, 1999, as supplemented by letter dated September 9, 1999.

*Brief description of amendment:* The amendment revised Technical Specification 3.4.11, "RCS Pressure and Temperature (PT) Limits," for 32 effective full power years (EFPY) using the latest vessel beltline material and fluence data.

*Date of issuance:* October 6, 1999.

*Effective date:* October 6, 1999.

*Amendment No.:* 159.

*Facility Operating License No. NPF-21:* The amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* May 19, 1999 (64 FR 27330).

The September 9, 1999, supplemental letter provided additional clarifying information, did not significantly expand the scope of the application as originally noticed and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 6, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

*Entergy Operations, Inc., Docket No. 50-313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas*

*Date of amendment request:* May 14, 1999, as supplemented by letters dated June 17, and September 7, 15, 17, and 24, 1999.

*Brief description of amendment:* The amendment revises the Technical Specification requirements affecting the surveillance criteria for that portion of the once-through steam generator tubes regarded as a primary-to-secondary pressure boundary located within the upper tubesheet and impacted by a specific degradation mechanism, namely, outside diameter intergranular attack.

*Date of issuance:* October 4, 1999.

*Effective date:* As of the date of issuance and shall be implemented prior to startup from the Unit 1 Cycle 15 refueling outage.

*Amendment No.:* 202.

*Facility Operating License No. DPR-51:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* June 2, 1999 (64 FR 29709).

The June 17, and September 7, 15, 17, and 24, 1999, letters provided clarifying and additional information that did not change the scope of the May 14, 1999, application and the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 4, 1999. No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

*Entergy Operations, Inc., Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana*

*Date of amendment request:* July 2, 1998, as supplemented by letters dated July 7 and August 24, 1999.

*Brief description of amendment:* The amendment changes the ACTION requirements for Technical Specification (TS) 3/4.3.2 for the Emergency Feedwater Actuation Signal (EFAS). This change revises the allowed outage time for a channel of EFAS to be in the tripped condition from "prior to entry into the applicable MODE(S) following the next COLD SHUTDOWN" to the more restrictive time limit of 48 hours and adds a shutdown requirement. Additionally, the TS 3.0.4 exemption is removed from the ACTION statement for the tripped condition. Changes to TS Bases Section 3/4.3.2 are also included to support the changes.

*Date of issuance:* October 6, 1999.

*Effective date:* As of the date of issuance and shall be implemented within 60 days from the date of issuance.

*Amendment No.:* 154.

*Facility Operating License No. NPF-38:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* December 16, 1998 (63 FR 69339). The July 7 and August 24, 1999, letters provided additional information that did not change the scope of the July 2, 1998, application and the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 6, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

*Florida Power and Light Company, et al., Docket No. 50-389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida*

*Date of application for amendment:* February 23, 1999.

*Brief description of amendment:* This amendment removes redundant boron concentration monitoring requirements specified for Modes 3 through 6 contained in TS 3/4.1.2.9, "Reactivity Control Systems-Boron Dilution."

*Date of Issuance:* October 4, 1999.

*Effective Date:* October 4, 1999.

*Amendment No.:* 104.

*Facility Operating License No. NPF-16:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 25, 1999 (64 FR 46440).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 4, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003.

*Florida Power Corporation, et al., Docket No. 50-302, Crystal River Nuclear Generating Plant, Unit 3, Citrus County, Florida*

*Date of application for amendment:* May 5, 1999, as supplemented May 21, May 28, August 20, and September 2, 1999.

*Brief description of amendment:* Changes the Crystal River Unit 3 Technical Specifications to allow an alternate repair criteria (ARC) for axial tube end crack-like indications in the upper and lower tubesheets of the Once-Through Steam Generators (OTSGs). The ARC will allow leaving OTSG tubes with axially oriented tube end cracks located within the clad region of the tube-to-tubesheet roll joint in service.

*Date of issuance:* October 1, 1999.

*Effective date:* October 1, 1999.

*Amendment No.:* 188.

*Facility Operating License No. DPR-72:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* June 2, 1999 (64 FR 29710). The May 21, May 28, August 20, and September 2, 1999, supplements did not affect the original no significant hazards consideration determination, or expand the scope of the amendment request as originally noticed.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* Coastal Region Library, 8619 W. Crystal Street, Crystal River, Florida 34428.

*Florida Power Corporation, et al., Docket No. 50-302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida*

*Date of application for amendment:* December 29, 1998, as supplemented June 18, 1999.

*Brief description of amendment:* Transfer of the license for Crystal River Unit 3, to the extent it is held by the City of Tallahassee, to Florida Power Corporation.

*Date of issuance:* October 1, 1999.

*Effective date:* October 1, 1999.

*Amendment No.:* 189.

*Facility Operating License No. DPR-31:* Amendment revised the License.



*Date of initial notice in Federal Register:* February 26, 1999 (64 FR 9544). The supplemental letter dated June 18, 1999, did not change the original proposed no significant hazards consideration determination, or expand the scope of the amendment request as originally noticed.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 8, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Coastal Region Library, 8619 W. Crystal River, Florida 34428.

*North Atlantic Energy Service Corporation, et al., Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire*

*Date of amendment request:* December 16, 1998.

*Brief description of amendment:* The amendment relocates Technical Specification (TS) 3/4.7.10 "Area Temperature Monitoring," and the associated TS Table 3.7-3, to the Technical Requirements Manual, which is referenced in the Seabrook Station Updated Final Safety Analysis Report and is the implementing manual for the TS improvement program referenced in Section 6.7 of the TSs.

*Date of issuance:* October 1, 1999.

*Effective date:* As of the date of issuance, and shall be implemented within 90 days.

*Amendment No.:* 63.

*Facility Operating License No. NPF-86:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* February 10, 1999 (64 FR 6700).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Exeter Public Library, Founders Park, Exeter, NH 03833.

*North Atlantic Energy Service Corporation, et al., Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire*

*Date of amendment request:* March 27, 1998, as supplemented by letter dated June 17, 1998.

*Brief description of amendment:* To revise Technical Specification (TS) 3.7.6.1, Control Room Emergency Makeup Air and Filtration, and TS 3.7.6.2, Control Room Air Conditioning, to delete the restriction to suspend all operations involving positive reactivity changes during the plant conditions specified.

*Date of issuance:* October 5, 1999.

*Effective date:* As of its date of issuance, and shall be implemented within 60 days.

*Amendment No.:* 64.

*Facility Operating License No. NPF-86:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* April 22, 1998 (63 FR 19973).

The June 17, 1998, supplement provided clarifying information and did not change the staff's proposed no significant hazards determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 5, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Exeter Public Library, Founders Park, Exeter, NH 03833.

*Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska*

*Date of amendment request:* March 31, 1999.

*Brief description of amendment:* The amendment revised Sections 2.10.4, 3.1, and Table 3-3 of the technical specifications to increase the minimum required reactor coolant system (RCS) flow rate and change surveillance requirements for RCS flow rate.

*Date of issuance:* October 6, 1999.

*Effective date:* October 6, 1999, to be implemented within 30 days from the date of issuance.

*Amendment No.:* 193.

*Facility Operating License No. DPR-40:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* May 19, 1999 (64 FR 27322).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 6, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102.

*PECO Energy Company, Public Service Electric and Gas Company Delmarva Power and Light Company, and Atlantic City Electric Company, Docket Nos. 50-277 and 50-278, Peach Bottom Atomic Power Station, Unit Nos. 2 and 3, York County, Pennsylvania*

*Date of application for amendments:* March 29, 1999, as supplemented July 21, 1999.

*Brief description of amendments:* The amendments delete the surveillance requirement (SR) associated only with the refuel platform fuel grapple fully

retracted position interlock input, which is currently required by the Peach Bottom Atomic Power Station, Units 2 and 3, Technical Specification SR 3.9.1.1.

*Date of issuance:* September 24, 1999.

*Effective date:* As of the date of issuance and shall be implemented within 30 days from the date of issuance.

*Amendments Nos.:* 229 and 232.

*Facility Operating License Nos. DPR-44 and DPR-56:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 11, 1999 (64 FR 43774).

The July 21, 1999, letter provided clarifying information that did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 24, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room location:* Government Publications Section, State Library of Pennsylvania, (Regional Depository) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, PA 17105.

*PECO Energy Company, Public Service Electric and Gas Company, Delmarva Power and Light Company, and Atlantic City Electric Company, Docket No. 50-278, Peach Bottom Atomic Power Station, Unit No. 3, York County, Pennsylvania*

*Date of application for amendment:* July 12, 1999, and supplemented August 30, 1999.

*Brief description of amendment:* The amendment changed the minimum critical power ratio safety limit and the approved methodologies referenced in the core operating limits report.

*Date of issuance:* October 5, 1999.

*Effective date:* As of date of issuance and shall be implemented prior to the start of Peach Bottom Atomic Power Station Unit No. 3, Cycle 13 operation.

*Amendment No.:* 233.

*Facility Operating License No. DPR-56:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 11, 1999 (64 FR 43777).

The August 30, 1999, letter provided additional information but did not change the initial proposed no significant hazards consideration determination or expand the amendment beyond the scope of the initial notice.



The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 5, 1999. No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Government Publications Section, State Library of Pennsylvania, (Regional Depository) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, PA 17105.

*Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California*

*Date of application for amendments:* September 10, 1998 (PCN-496), as supplemented July 19, 1999.

*Brief description of amendments:* The amendments delete Technical Specification 3.6.7 relating to hydrogen recombiners.

*Date of issuance:* October 7, 1999.

*Effective date:* October 7, 1999, to be implemented within 30 days of issuance.

*Amendment Nos.:* Unit 2—159; Unit 3—150.

*Facility Operating License Nos. NPF-10 and NPF-15:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 11, 1999 (64 FR 43778).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 7, 1999.

No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Main Library, University of California, P.O. Box 19557, Irvine, California 92713.

*Southern Nuclear Operating Company, Inc., Docket Nos. 50-348 and 50-364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama*

*Date of amendments request:* November 6, 1998.

*Brief Description of amendments:* The amendments revise the TS nuclear instrumentation system (NIS) surveillance requirements. The revised TS changes require Southern Nuclear Company to adjust the NIS power range channels only when calorimetric-calculated power is greater than the power range indicated power by more than +2 percent rated thermal power. The proposed TS changes are for both the current TS and the improved TS.

*Date of issuance:* October 1, 1999.

*Effective date:* As of the date of issuance and shall be implemented within 30 days from the date of issuance.

*Amendment Nos.:* 144 and 135  
*Facility Operating License Nos. NPF-2 and NPF-8:* Amendments revise the Technical Specifications.

*Date of initial notice in Federal Register:* January 27, 1999 (64 FR 4160).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Houston-Love Memorial Library, 212 W. Burdeshaw Street, Post Office Box 1369, Dothan, Alabama.

*Southern Nuclear Operating Company, Inc., et al., Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia*

*Date of application for amendments:* April 13, 1999, as supplemented by letter dated August 26, 1999.

*Brief description of amendments:* The amendments revise Technical Specifications (TS) to update Limiting Condition for Operation (LCO) 3.0.4 and Surveillance Requirements (SR) 3.0.4 in the existing TS to be consistent with the versions of the LCO 3.0.4 and SR 3.0.4 as they appear in Revision 1 to NUREG-1431. The proposed change also adds the words "or that are part of a shutdown of the unit," to LCO 3.0.4 to allow reactor shutdowns that are not necessarily required by other TS Required Actions.

*Date of issuance:* September 30, 1999.

*Effective date:* As of the date of issuance and shall be implemented within 30 days from the date of issuance.

*Amendment Nos.:* Unit 1—108; Unit 2—86.

*Facility Operating License Nos. NPF-68 and NPF-81:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 11, 1999 (64 FR 43779).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 30, 1999.

No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Burke County Library, 412 Fourth Street, Waynesboro, Georgia.

*Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia*

*Date of application for amendments:* July 29, 1999.

*Brief description of amendments:* The amendments revise TS Section 3.1.7,

"Standby Liquid Control (SLC) System." The revision replaces "greater than the Region B limits," which could be misleading, with "within the Region B limits."

*Date of issuance:* September 24, 1999.

*Effective date:* As of the date of issuance and shall be implemented within 30 days from the date of issuance.

*Amendment Nos.:* Unit 1—217; Unit 2—158.

*Facility Operating License Nos. DPR-57 and NPF-5:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 25, 1999 (64 FR 46449). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 24, 1999.

No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Appling County Public Library, 301 City Hall Drive, Baxley, Georgia.

*Tennessee Valley Authority, Docket No. 50-296, Browns Ferry Nuclear Plant, Unit 3, Limestone County, Alabama*

*Date of application for amendment:* July 28, 1999 (TS-398).

*Brief description of amendment:* The amendment revises the Technical Specifications (TS) to implement operability and surveillance requirements for the previously-installed Oscillation Power Range Monitor trip function.

*Date of issuance:* September 27, 1999.

*Effective date:* As of the date of issuance, to be implemented at the end of the Cycle 9 outage.

*Amendment No.:* 221.

*Facility Operating License No. DPR-68:* Amendment revises the TS.

*Date of initial notice in Federal Register:* August 25, 1999 (64 FR 46450). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 27, 1999.

No significant hazards consideration comments received: No.

**Local Public Document Room**  
*location:* Athens Public Library, South Street, Athens, Alabama 35611.

*Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee*

*Date of application for amendments:* February 26, 1999 (TS 98-08).

*Brief description of amendments:* The amendments relocate Sequoyah Nuclear

Plant Technical Specification (TS) 3.7.6, "Flood Protection Plan," and its associated bases from the TS to the Technical Requirements Manual. Future changes to the Flood Protection Plan will be processed in accordance with 10 CFR 50.59.

*Date of issuance:* October 6, 1999.

*Effective date:* As of the date of issuance to be implemented no later than 45 days after issuance.

*Amendment Nos.:* 247 and 238.

*Facility Operating License Nos. DPR-77 and DPR-79:* Amendments revise the TS.

*Date of initial notice in Federal*

*Register:* March 24, 1999 (64 FR 14286)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 6, 1999.

No significant hazards consideration comments received: No.

*Local Public Document Room*

*location:* Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

*Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont*

*Date of application for amendment:* July 20, 1999, as supplemented August 13, 1999.

*Brief description of amendment:* The amendment modifies the operability requirements for the high pressure cooling systems—High Pressure Coolant Injection (HPCI), Reactor Core Isolation Cooling (RCIC), and Automatic Depressurization System (ADS)—and the safety and relief valves, and adds a time limitation for conducting operability testing of HPCI and RCIC.

*Date of Issuance:* October 1, 1999.

*Effective date:* As of the date of issuance, and shall be implemented within 30 days.

*Amendment No.:* 177

*Facility Operating License No. DPR-28:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal*

*Register:* August 31, 1999 (64 FR 47537)

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No

*Local Public Document Room*

*location:* Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301.

*Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear*

*Power Station, Vernon, Vermont*

*Date of application for amendment:* June 29, 1999

*Brief description of amendment:* The amendment revises the leak rate requirements for the main

steam line isolation valves. Specifically, a total allowable leakage rate for the sum of the four main steam lines is established that is equal to four times the current allowable individual main steam line isolation valve leakage rate. The allowable individual main steam line isolation valve leakage rate is revised to be one half of the allowable total leakage rate.

*Date of Issuance:* October 1, 1999.

*Effective date:* 10/01/99, and shall be implemented within 30 days.

*Amendment No.:* 178

*Facility Operating License No. DPR-28:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal*

*Register:* July 28, 1999 (64 FR 40909).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated October 1, 1999.

No significant hazards consideration comments received: No

*Local Public Document Room*

*location:* Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 13th day of October, 1999.

**John A. Zwolinski,**

*Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 99-27210 Filed 10-19-99; 8:45 am]

BILLING CODE 7590-01-P

## POSTAL SERVICE

### Notice of Meeting

**AGENCY:** Postal Service.

**ACTION:** Notice of meeting.

**SUMMARY:** The Postal Service will hold further meetings of a Consensus Committee to develop recommendations for revision of USPS STD 7A, which governs the design of curbside mailboxes. The committee will develop and adopt its recommendations through a consensus process. The committee will consist of persons who represent the interests affected by the proposed rule, including mailbox manufacturers, mailbox accessory manufacturers, and postal customers.

**MEETING DATES:** The second and third committee meetings are tentatively scheduled for November 3-4, 1999 and December 14-15, 1999.

**MEETING PLACE:** U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW, Washington, DC 20260.

**FOR FURTHER INFORMATION CONTACT:** Annamarie Gildea, (202) 268-3558.

**SUPPLEMENTARY INFORMATION:** Mail comments and all other communications regarding the

committee to Annamarie Gildea, U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW, Room 7142, Washington, DC 20260. Committee documents will be available for public inspection and copying between 9 a.m. and 4 p.m. weekdays at the address above. Entry into U.S. Postal Service Headquarters is controlled. Persons wishing to attend the November 3-4 meeting must send a fax to Annamarie Gildea at (202) 268-5293 no later than October 29, 1999 with the person's name and organizational affiliation, if any. Persons wishing to attend the December 14-15 meeting must fax the same information to the same name and number no later than December 10, 1999. For additional information regarding the USPS STD 7A Consensus Committee, see **Federal Register** Vol 64, No. 158, p. 44681 (August 17, 1999).

**Neva R. Watson,**

*Alternate Certifying Officer, Legislative.*

[FR Doc. 99-27344 Filed 10-19-99; 8:45 am]

BILLING CODE 7710-12-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42002; File No. SR-OPRA-99-1]

### Options Price Reporting Authority; Notice of Filing of Amendment to OPRA Plan Adopting a Participation Fee Payable by Each New Party to the Plan

October 13, 1999.

Pursuant to Rule 11Aa3-2 under the Securities Exchange Act of 1934 ("Exchange Act"),<sup>1</sup> notice is hereby given that on August 16, 1999, the Options Price Reporting Authority ("OPRA")<sup>2</sup> submitted to the Securities and Exchange Commission ("SEC" or "Commission") an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information ("Plan"). The amendment adds provisions applicable to a participation fee payable by each

<sup>1</sup> 17 CFR 240.11Aa3-2.

<sup>2</sup> OPRA is a National Market System Plan approved by the Commission pursuant to Section 11A of the Exchange Act and Rule 11Aa3-2 thereunder. See Securities Exchange Act Release No. 17638 (Mar. 18, 1981).

The Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the member exchanges. The five exchanges which agreed to the OPRA Plan are the American Stock Exchange ("AMEX"); the Chicago Board Options Exchange ("CBOE"); the New York Stock Exchange ("NYSE"); the Pacific Exchange ("PCX"); and the Philadelphia Stock Exchange ("Phlx").

new party to the Plan and codifies procedures applicable to the admission of new parties to the Plan. The Commission is publishing this notice to solicit comments from interested persons on the proposed Plan amendment.

### **I. Description and Purpose of the Amendment**

Currently, the OPRA Plan provides that any national securities exchange or registered securities association whose rules governing the trading of standardized options have been approved by the Commission may become a party to the Plan, provided it agrees to conform to the terms and conditions of the Plan. However, the Plan is silent concerning procedural aspects of the application process, and it is likewise silent concerning what, if any, participation fee must be paid by an exchange at the time it becomes a party to the Plan. The purpose of the amendment is to incorporate in the Plan certain application forms and procedures used to apply to become a party to the Plan and to obtain interim access to the OPRA system and to the OPRA Processor for planning and testing purposes even before an applicant becomes a party to the Plan. The amendment also proposes to add to the OPRA Plan provisions for a one-time participation fee payable by each new party to the Plan.

OPRA believes it is appropriate to require new parties to the Plan to pay a one time participation fee, in recognition of the significant value to a new party of participation in OPRA. Absent such a participation fee, this value would in effect be contributed to the new party by the existing parties to the Plan, who have been responsible for the development of OPRA's systems and infrastructure. In fact, the OPRA Plan at one time did include provisions that required all new parties to pay a one-time participation fee based on a share of OPRA's unamortized "start-up" cost at the time of admission. However, during most of OPRA's history, unamortized start-up or developmental costs have been at or close to zero, because these costs are generally expensed as they are incurred, and those costs that were capitalized were amortized over a five year period. Thus a participation fee based on unamortized start-up costs most of the time was unrealistically low or even zero. Accordingly this provision was eliminated from the Plan in 1995, when a number of other changes were made to financial provisions of the Plan. At that time, OPRA anticipated formulating a more appropriate way to determine

what should be the participation fee for new parties and amending the Plan at a later date to reflect such a fee. In the absence of any applications from new participants until recently, OPRA has not focused on this issue until now.

In response to the application recently received from the International Securities Exchange ("ISE") and in anticipation of the receipt of additional applications from other new exchanges, OPRA has now considered the question that was left open when the original participation fee provisions were removed from the Plan. Because there are so many factors that may be relevant to a determination of the amount to be paid by an exchange seeking to be a party to the Plan, OPRA has concluded that instead of requiring the same fixed amount to be paid by every applicant regardless of the nature of its proposed options market, the Plan should provide flexibility by setting forth a general statement of the factors that may be taken into account in determining the amount of the fee. The actual amount of the fee in each separate instance would then be determined by the parties in discussion with the applicant under the general oversight of the Commission. This same approach is reflected in the Plans of other registered securities information processors, such as the Consolidated Tape Association ("CTA") and the consolidated Quotation system ("CQ"), and it provides the flexibility needed to allow all of the interested parties to reach agreement on the amount of the participation fee within an appropriately structured process.<sup>3</sup>

Therefore, OPRA proposes to amend the OPRA Plan to provide that each new party to the Plan will pay to the other parties a participation fee "that attributes an appropriate value to the assets, both tangible and intangible, that OPRA has created and will make available to the new party." The Plan will then list the factors that may be considered in arriving at this value, as follows: an independent valuation assigned to the grant of access; previous valuations approved by the parties; an assessment of costs already contributed by the existing parties to the creation and continuation of OPRA facilities; the new party's reasonably anticipated demands on the OPRA system capacity; an assessment of costs reasonably expected to be incurred by the OPRA Processor in modifying the OPRA system and network to accommodate the new party; and such other historical

<sup>3</sup> See Section III(c) of the Second Restatement of the CTA Plan as restated December 1995, and Section III(c) of the Restatement of the CQ Plan as restated December 1995.

and entry-cost factors as reasonably may be included in an assessment of the value of participation. The language proposed to be included in the OPRA Plan in this respect is virtually identical to language currently included in the CTA and CQ Plans, as referenced above.

Once the Plan is amended as proposed herein, OPRA anticipates discussing directly with each applicant how the enumerated factors should apply to a determination of the amount of the participation fee to be paid by that applicant, in an effort to reach agreement as to the amount of the fee. If an applicant does not agree with the amount of the participation fee proposed to be charged by OPRA, OPRA will provide notice to the Commission of the failure to agree, and acknowledges that the subject of the amount of the participation fee would be subject to review by the Commission, pursuant to Section 11A(b)(5) of the Exchange Act.<sup>4</sup>

The proposed Plan amendments also clarify what has been OPRA's past practice by providing that a person proposing to operate an options market may apply to become a party even before the entity is registered as a national securities exchange or registered securities association or before the options rules of an existing exchange or association are approved by the Commission. Such an applicant may also apply for limited access to OPRA for planning and testing purposes by submitting a separate application for such access and by making a refundable deposit in the amount of \$100,000, to be applied to payment of the agree-upon participation fee when the applicant becomes a party or, if the application is withdrawn, or if for any other reason the applicant does not become a party, to be refunded to the applicant after reimbursing OPRA for any costs incurred by it or its processor in processing the application and testing with the applicant. The text of the proposed Plan amendment and the application forms proposed to be used for these purposes are available at the principal offices of OPRA and at the Commission.

### **II. Implementation of the Plan Amendment**

OPRA intends to make the proposed amendments to the OPRA Plan reflected in this filing (*i.e.*, the participation fee and the application forms) effective concurrently, immediately upon the approval of the amendment by the Commission, pursuant to Rule 11Aa3-2 under the Exchange Act. As soon as the

<sup>4</sup> 17 CFR 240.11A(b)(5).

amendments are effective, OPRA intends to commence discussions with ISE concerning the amount of the participation fee.

### III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed Plan amendment is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. Copies of the submission, all subsequent amendments, and 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 withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available at the principal offices of OPRA. All submissions should refer to file number SR-OPRA-99-1 and should be submitted by November 10, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>5</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

[FR Doc. 99-27368 Filed 10-19-99; 8:45 am]

BILLING CODE 8010-01-M

### SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

#### Las Vegas Entertainment Network Inc.; Order of Suspension of Trading

October 15, 1999.

It appears to the Securities and Exchange Commission that there is a lack of current, adequate and accurate information concerning the securities of Las Vegas Entertainment Network, Inc., a Delaware corporation. Questions have been raised about the adequacy and accuracy of publicly disseminated information concerning, among other things, an agreement to receive \$190 million in cash from two investors.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period from 9:30 a.m. EDT, October 18, 1999, through 11:59 p.m. EDT, on October 29, 1999.

By the Commission:

**Jonathan G. Katz,**  
Secretary.

[FR Doc. 99-27469 Filed 10-18-99; 12:11 pm]

BILLING CODE 8010-01-M

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-41999; File No. SR-Amex-98-33]

#### Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change by American Stock Exchange LLC Regarding a Pilot Program Relating to Rule 462 (Minimum Margins) Applicable to Portfolio Depositary Receipts and Index Fund Shares

October 13, 1999.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> notice is hereby given that on September 18, 1998, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change described in Items I, II, and III below, which Items have been prepared by the Amex. Amex amended the proposal twice on March 4, 1999.<sup>2</sup> The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes amending that portion of Exchange Rule 462 addressing the required margin for certain short index options positions covered by positions in Portfolio Depositary Receipts ("PDRs") or Index Fund Shares.<sup>3</sup> The Exchange requests

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> The Commission received two amendments from the Exchange dated March 4, 1999. See Notice of Filing of Amendment No. 1 to a Proposed Rule Change by American Stock Exchange LLC Relating to Rule 462 (Minimum Margins) Applicable to Portfolio Depositary Receipts and Index Fund Shares ("Amendment No. 1") and letter from Michael Cavalier, Associate General Counsel, Legal & Regulatory Policy, Exchange to Michael A. Walinskas, Deputy Associate Director, Division of Market Regulation ("Division"), Commission ("Amendment No. 2").

<sup>3</sup> PDRs are shares in a unit investment trust created under state or other local law, whose assets

that the proposed rule change be approved on an accelerated basis and that it be implemented as a one-year pilot program. The text of the proposed rule change is as follows, with [brackets] indicating words to be deleted and *italics* indicating words to be added:

#### Minimum Margins

\* \* \* \* \*

#### Rule 462(d)(2)(H)(iv)

*No margin need be required in respect of a call index option contract carried in a short position where there is carried for the same account a long position in Portfolio Depositary Receipts or Index Fund Shares as specified in Commentary .10 to this Rule, having a market value at least equal to the aggregate current index value of the stocks underlying the index options contracts to be covered.*

*No margin need be required in respect of a put index option contract carried in a short position where there is carried for the same account a short position in Portfolio Depositary Receipts or Index Fund Shares as specified in Commentary .10 to this Rule, having a market value at least equal to the aggregate current index value of the stocks underlying the index options contracts to be covered.*

*The term "aggregate current index value" shall have the meaning set forth in Rule 900C.*

*In computing margin on an existing position in Portfolio Depositary Receipts or Index Fund Shares covering a "short" put or "short" call, the market value of such Portfolio Depositary Receipts or Index Fund Shares to be used shall not be greater than the exercise price in the case of a call or less than the market value of such Portfolio Depositary Receipts or Index Fund Shares in the case of a put and the required margin shall be increased by an unrealized loss on the short security position.*

*[(iv)] (v) No change other than renumbering.*

#### Commentary

.10 Under the provisions of subparagraph (H)(iv) of paragraph (d)(2) of this Rule regarding margin requirements applicable to positions in index options and Portfolio Depositary Receipts or Index Fund Shares: (1) positions in Standard & Poor's Depositary Receipts® ("SPDRs®") *shall be cover for positions in S&P 500® Index options (SPX), S&P 100® Index*

are a securities portfolio. Index Fund Shares are shares in an open-end management investment company registered under the Investment Company Act of 1940, as amended, whose assets are a securities portfolio.

<sup>5</sup> 17 CFR 200.30-3(a)(29).

options (OEX) or Institutional Index options (XII); (2) positions in MidCap SPDRs<sup>TM</sup> shall be cover for positions in S&P MidCap 400 Index<sup>TM</sup> options (MID); (3) positions in DIAMONDS<sup>TM</sup> shall be cover for positions in Dow Jones Industrial options (DIJ) or Major Market Index options (XMI); and (4) positions in Nasdaq-100 Shares<sup>SM</sup> shall be cover for positions in Nasdaq-100<sup>®</sup> Index options (NDX).

\* \* \* \* \*

## 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 Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The filing proposes to amend Amex Rule 462(d)(2)(H)(iv) and to adopt Commentary .10 to Rule 462 to permit PDRs<sup>4</sup> and Index Fund Shares traded on the Exchange under Amex Rules 1000 and 1000A, respectively, to serve as cover for certain short index options positions. Specifically, proposed Rule 462(d)(2)(H)(iv) would provide that no additional margin is required in respect of a call index option carried in a short position where the same account is long PDRs or Index Fund Shares as specified in proposed Commentary .10. Similarly, no additional margin would be required in respect of a short put index option contract where the account has a short position in PDRs or Index Fund Shares as specified in proposed Commentary .10. In either case, the PDR or Index Fund Shares position would be required to have a market value at least equal to the aggregate current index value, as defined in Amex rule 900C,<sup>5</sup> of stocks underlying the index options contracts to be covered.<sup>6</sup>

<sup>4</sup> "PDR" is a service mark of PDR Services LLC, a Delaware limited liability company whose sole member is the American Stock Exchange LLC.

<sup>5</sup> See *infra* note 10 defining aggregate current index value.

<sup>6</sup> Current subparagraph (iv) of Rule 462(d)(2)(H) would be renumbered as subparagraph (v).

In letters dated August 19, 1992, and January 14, 1993, to staffs of the SEC and the Board of Governors of the Federal Reserve System ("Federal Reserve"), respectively, the Exchange proposed certain margin treatment for Standard & Poor's Depository Receipts based on the S&P 500 Index<sup>®</sup>.<sup>7</sup> The Exchange proposed that, with respect to positions that are hedged or offset, where one leg of the position consists of SPDRs and the other leg is an Options Clearing Corporation-issued option on a broad-based stock index with at least a 99% correlation with the S&P 500 Index, such position be treated as the equivalent of covered equity options. Specifically, the Exchange requested that no additional margin be required in respect of a short index call position when a long position in SPDRs is carried for the same account, and in respect of a short index put position when a short position in SPDRs is carried for the same account. The Federal Reserve stated that the Exchange's proposed margin requirements were compatible with then-current Regulation T.<sup>8</sup> Thereafter, the Federal Reserve took a comparable position with respect to MidCap SPDRs,<sup>TM</sup> based on the S&P MidCap 400 Index<sup>TM</sup>.<sup>9</sup>

The Exchange proposes to incorporate the offsets and cover for short index options positions to those described in the Federal Reserve's February 1993 letter into Amex Rule 462, as well as to add comparable treatment for positions in DIJ, XMI and NDX options, as identified in proposed new Commentary .10 to Rule 462. Proposed Rule

<sup>7</sup> See letter dated August 19, 1992 from James M. McNeil, Chief Examiner, Amex, to Sharon M. Lawson, Assistant Director, Division, SEC; letter dated January 14, 1993 from James M. McNeil, Chief Examiner, Amex, to Laura M. Homer, Division of Supervision and Regulation, Federal Reserve.

<sup>8</sup> See letter dated February 1, 1993 from Michael J. Schoenfeld, Senior Securities Regulation Analyst, Federal Reserve, to James M. McNeil, Chief Examiner, Amex.

<sup>9</sup> The Amex represents that the Federal Reserve orally confirmed this position by telephone call between James M. McNeil, Amex and Michael Schoenfeld, Federal Reserve on May 1, 1995. In connection with the commencement of trading in DIAMONDS<sup>SM</sup> Trust Units, the Amex also requested confirmation from the Federal Reserve that margin treatment of DIAMONDS would be comparable to that for SPDRs under Regulation T. Instead of providing such confirmation, the Federal Reserve, in its January 8, 1998 letter to the Amex regarding application of Regulation T to DIAMONDS noted that Section 220.18 of Regulation T, (the Supplement to Regulation T), amended effective June 1, 1997, provides that the margin requirements for options is "the amount or other position" specified by the national securities exchange that trades the option (for listed options). See letter from Scott Holz, Senior Attorney, Federal Reserve, to James M. McNeil, Chief Examiner, Amex, dated January 8, 1998.

462(d)(2)(H)(iv) provides that no additional margin is required in respect of a call index option contract carried in a short position where there is carried for the same account a long position in PDRs or Index Fund Shares as specified in Commentary .10 that has a market value at least equal to the aggregate current index value of the stocks underlying the index options contracts to be covered. In addition, no margin is required in respect of a put index options contract carried in a short position where there is carried for the same account a short position in PDRs or Index Fund Shares as specified in Commentary .10 that has a market value at least equal to the aggregate current index value of the stocks underlying the index options contracts to be covered.<sup>10</sup>

Proposed Commentary .10 to Rule 462 specifies the PDRs or Index Fund Shares which qualify for margin treatment under Rule 462(d)(2)(H)(iv), together with the specific index options that such PDRs or Index Fund Shares can offset or cover for margin purposes.<sup>11</sup> Proposed Commentary .10 specifies that: (1) positions in Standard & Poor's Depository Receipts<sup>®</sup> ("SPDRs<sup>®</sup>") shall be covered for positions in S&P 500<sup>®</sup> Index options (SPX), S&P 100<sup>®</sup> Index options (OEX) or Institutional Index options (XII); (2) positions in MidCap SPDRs<sup>TM</sup> shall be covered for positions in S&P MidCap 400 Index<sup>TM</sup> options (MID); (3) positions in DIAMONDS<sup>TM</sup> shall be cover for positions in Dow Jones Industrial options (DIJ) or Major Market Index options (XMI); and (4) positions in Nasdaq-100 Shares<sup>SM</sup> shall be cover for positions in Nasdaq-100<sup>®</sup> Index options (NDX). The Exchange points out that these proposed offsets in Commentary .10 apply only to indexes and PDRs or Index Fund Shares with a high degree of correlation, both in performance (return on investments) and in the collection of securities underlying such indexes, PDRs and Index Fund shares.

<sup>10</sup> "Aggregate current index value" means the "current index group value" multiplied by the "index multiplier."

The "current index group value" is \$1.00 multiplied by the total of the current prices of all stocks in an index after each stock's current price is multiplied by a factor representing that stock's weight in the index.

The "index multiplier" is a number (determined when the PDR or Index Fund Share is created) that the trading level of the corresponding index (*i.e.*, the Dow at 9926.2) is multiplied by to reduce it to an appropriate trading amount. For example, when the Dow trades at 9926.2, a DIAMONDS share trades at \$99.26. Thus, the index multiplier is .01.

See Amex Rule 900C.

<sup>11</sup> The rule does not apply to margin with respect to long or short positions in PDRs and Index Fund Shares.

The Exchange believes it is appropriate for the index options specified in proposed Commentary .10 to be offset by the specified PDRs because the index options and PDRs are based on the same underlying securities, or related to indexes whose underlying securities include all securities underlying another index (i.e., S&P 100® Index and the S&P 500® Index) or indexes that have a high degree of overlap of securities underlying the indexes and that have historically demonstrated a very high correlation in price changes (i.e., the Institutional Index and the S&P 500® Index; the Major Market Index and the Dow Jones Industrial Average). The Exchange will propose additions to or deletions from Commentary .10 by a filing with the Commission pursuant to Rule 19b-4.

#### (1) Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general and furthers the objectives of Section 6(b) in particular in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposed rule change will impose no burden on competition.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received with respect to the proposed rule change.

#### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The Exchange requests that the Commission grant accelerated effectiveness to the proposed rule change pursuant to Section 19(b) of the Act. Amex represents that the proposed rule is similar in effect to the position taken previously by the Federal Reserve in correspondence with Amex, as cited above, in connection with trading of PDRs on the Exchange. Amex further requests that the proposed rule be implemented as a one-year pilot program.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing,

including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW, Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. File Number SR-AMEX-98-33 should be included on the subject line if E-mail is used to submit a comment letter. Electronically submitted comment letters will be posted on the Commission's Internet web site (<http://www.sec.gov>). All submissions should refer to File Number SR-AMEX-98-33 and should be submitted by November 10, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>12</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 99-27367 Filed 10-19-99; 8:45 am]

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#### **SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-41995; File No. SR-CBOE-99-29]

#### **Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendments No. 1 and No. 2 to Proposed Rule Change by the Chicago Board Options Exchange, Inc. To Allow RAES Orders To Trade Against Orders in the Exchange's Limit Order Book**

October 8, 1999.

#### **I. Introduction**

On June 23, 1999, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") submitted to the Securities and Exchange Commission

("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4<sup>2</sup> thereunder, a proposed rule change. In its proposal, the CBOE seeks to amend its rules to allow Retail Automatic Execution System ("RAES") orders to trade directly against orders in the Exchange's limit order book. The proposed rule change was published for comment in the **Federal Register** on July 22, 1999.<sup>3</sup> On August 11, 1999, the CBOE filed Amendment No. 1 to the proposed rule change.<sup>4</sup> On September 23, 1999, the CBOE filed Amendment No. 2 to the proposed rule change.<sup>5</sup> The Commission received one comment on the proposal.<sup>6</sup> This order approves the proposal, as amended. In addition, the Commission is publishing this notice to solicit comments on Amendments No. 1 and No. 2 to the proposed rule change and is simultaneously approving Amendments No. 1 and No. 2 on an accelerated basis.

#### **II. Description of the Proposal**

The Exchange is developing a system, the Automated Book Priority system, that will allow an order entered into RAES to trade directly with an order on the Exchange's customer limit order book in those cases where the prevailing market bid or offer is equal to the best bid or offer on the Exchange's book.<sup>7</sup> Currently, when a RAES order is

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 41621 (July 14, 1999), 64 FR 39546.

<sup>4</sup> In Amendment No. 1, the CBOE makes technical, non-substantive changes to the proposal. The CBOE resubmitted the text of the Exchange Rules to show the actual text of these rules as of the date the proposed rule change was submitted. See letter from Timothy Thompson, Director, Regulatory Affairs, CBOE, to Michael Walinskas, Associate Director, Division of Market Regulation ("Division"), Commission, dated August 10, 1999 ("Amendment No. 1").

<sup>5</sup> In Amendment No. 2, the CBOE makes additional technical, non-substantive changes to the proposal. The CBOE resubmitted the proposed rule text to reflect amendments to existing rule text from a separate filing (SR-CBOE-99-17) that was approved by the Commission on August 23, 1999. See Securities Exchange Act Release No. 41782, 64 FR 47881 (Sept. 1, 1999). In addition, the CBOE clarifies that portions of rule text approved by SR-CBOE-99-17 will be removed by this proposed rule change. See letter from Timothy Thompson, Director, Regulatory Affairs, CBOE, to Ken Rosen, Attorney, Division, Commission, dated September 22, 1999 ("Amendment No. 2").

<sup>6</sup> In approving the proposal, the Commission has considered the commenter's support of the proposed rule change. See letter from Gerald D. Putnam, Chief Executive Officer, Archipelago, L.L.C., to Jonathan G. Katz, Secretary, Commission, dated August 13, 1999.

<sup>7</sup> In the event that the order in the book is for a smaller number of contracts than the RAES order, the balance of the RAES order will be assigned to participating market-makers at the same price at which the rest of the order was executed.

<sup>12</sup> 17 CFR 200.30-3(a)(12).

entered into the Exchange's Order Routing System at a time when the prevailing market bid or offer is equal to the best bid or offer on the Exchange's book, the order is routed electronically (i.e., "kicked out") to a Floor Broker's terminal or work station in the crowd subject to the volume parameters of each firm. This allows for manual representation of the order in the crowd and generally prevents orders from trading through the book.<sup>8</sup> The orders are kicked out because CBOE Rule 6.45 provides that bids or offers displayed on the customer limit order book are entitled to priority over other bids or offers at the same price.

To implement the Automated Book Priority system, the CBOE proposes to amend paragraphs (b) and (c) of CBOE Rule 6.8, "*RAES Operations in Equity Options*," to provide for RAES orders to trade directly against orders entered in the Exchange's customer limit order book. The Exchange also proposes to delete Interpretation .04 of CBOE Rule 6.8 which concerns how orders that have been kicked out pursuant to the current paragraph (c) should be handled.

The CBOE believes that the Automated Book Priority system will both prevent the RAES order from becoming subject to market risk and preserve the priority of the booked order. Thus, the proposed rule change will benefit customers using the RAES system as well as those whose orders are in the Exchange's book because both categories of orders will be executed more quickly than they would have been executed otherwise.

The Exchange anticipates that the Automated Book Priority system will be ready to be implemented by October 31, 1999.<sup>9</sup> The Exchange will provide its membership with prior notice by means of a Regulatory Circular informing them of the date the system and the rule change will be implemented.

### III. Discussion

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the

Act.<sup>10</sup> In particular, the Commission finds the proposal is consistent with Section 6(b)(5)<sup>11</sup> of the Act. Section 6(b)(5) requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade and to protect investors and the public interest.

The Commission believes that the proposed rule change will benefit investors by allowing RAES orders to trade against orders in the Exchange's limit order book. Currently, when a RAES order is entered at a time when the prevailing market bid or offer is equal to the best bid or offer of the Exchange's limit order book, the order is kicked out into the crowd for manual execution. Although this generally prevents RAES orders from trading through the book, when a RAES order is kicked out to the crowd, it may become subject to market risk, which can be significant in a fast moving market. Moreover, the kick out feature is not employed for IBM, DJX, and OEX options, where RAES orders can trade through the book. The Commission finds that the implementation of this new system will provide for more efficient execution of both RAES and booked orders. Investors should benefit from more efficient executions, while the priority of booked orders is maintained.

Linking the Exchange's limit order book to the RAES system is important to ensure proper quality of execution of RAES orders and booked limit orders. Implementation is particularly important for limit orders on IBM, DJX, and OEX options, where booked orders may receive delayed or no execution. The Commission expects that the Exchange will take all reasonable steps necessary to implement the proposal by October 31, 1999.

The Commission finds good cause for approving Amendments No. 1 and No. 2 prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. In Amendment No. 1, the CBOE merely clarified the text of the Exchange Rules to show the actual text of these rules as of the date the proposed rule change was submitted. In Amendment No. 2, the CBOE resubmitted the text of the Exchange Rules to show the text of these rules as amended by filing (SR-CBOE-99-17) that was approved by the Commission on August 23, 1999.<sup>12</sup> In addition, the CBOE explains that portions of the rule

text approved by SR-CBOE-99-17 will be removed by this proposed rule change. Therefore, the amendments did not substantively alter the proposal.

### IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>13</sup> that the proposed rule change (SR-CBOE-99-29), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>14</sup>

**Margaret H. McFarland**,  
Deputy Secretary.

[FR Doc. 99-27371 Filed 10-19-99; 8:45 am]

BILLING CODE 8010-01-M

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42004; File No. SR-CHX-99-16]

### Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of Proposed Rules Change and Amendment Nos. 1 and 2 by the Chicago Stock Exchange Relating to the Implementation of an Extended Hours Trading Session

October 13, 1999.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 14, 1999, the Chicago Stock Exchange, Incorporated ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the CHX. On October 7, 1999, the CHX submitted Amendment No. 1 to the proposed rule change.<sup>3</sup> On October 8, 1999, the CHX filed Amendment No. 2 to the proposed rule change.<sup>4</sup> The

<sup>13</sup> 15 U.S.C. 78s(b)(2).

<sup>14</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> Letter to Katherine A. England, Assistant Director, Division of Market Regulation ("Division"), Commission, from Paul B. O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, dated October 5, 1999 ("Amendment No. 1"). In Amendment No. 1, the CHX proposes to amend the initial filing to request that the Commission approve its proposed extended hours trading session on a pilot basis through March 1, 2000.

<sup>4</sup> Letter to Katherine A. England, Assistant Director, Division, Commission, from Paul B. O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, dated October 7, 1999 ("Amendment No. 2"). In Amendment No. 2, the CHX proposes that, although effective upon

<sup>8</sup> Currently, RAES orders in options on IBM, the Dow Jones Industrial Average (DJX), and the Standard & Poor's 100 Stock Index (OEX) may be executed on RAES even where the prevailing market bid or offer equals the best bid or offer on the Exchange's book. Upon the implementation of the Automated Book Priority system, RAES orders in these option classes, like all other option classes, will trade against orders in the book in these circumstances.

<sup>9</sup> Telephone call between Timothy Thompson, Director, Regulatory Affairs, CBOE, and Joseph P. Corcoran, Attorney, Division, Commission, on August 25, 1999.

<sup>10</sup> In addition, pursuant to Section 3(f) of the Act, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>11</sup> 15 U.S.C. 78f(b)(5).

<sup>12</sup> See *supra* note 5.



Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and to grant accelerated approval to the proposed rule change and Amendment Nos. 1 and 2 on a pilot basis through March 1, 2000.

### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change.**

The Exchange proposes to add new Article XXA to the Exchange's Rules to implement an extended hours trading session (the "E-Session<sup>TM</sup>") on a pilot basis through March 1, 2000. The Exchange also proposes to amend the following rules to reflect changes to trading times and to various procedures that arise because of the E-Session: Article IX, Rule 10(b); Article XX, Rules 1, 2 and 37; Article XXI, Rule 1; Article XXXI, Rules 6 and 9; and Article XXXIV. Below is the text of the proposed rule change. Proposed new language is italicized; proposed deletions are in brackets;

#### **Article XXA—Trading Rules and Procedures Applicable To Equity Trading During the Extended Trading Session**

##### **Introduction**

*The trading rules and procedures in this Article shall apply to trading conducted on the Exchange during the Extended Trading Session (the "E-Session"). Unless otherwise defined in this Article, capitalized terms used in this Article shall have the same meanings given them elsewhere in the Rules. Except where the context requires otherwise, the provisions of the Constitution and all other Rules and policies of the Board of Governors, including those that apply to trading conducted during the Primary Trading Session (the "PTS"), shall continue to be applicable to trading during the E-Session. If any rule in this Article is inconsistent with any other provisions of the Rules, the provisions of this Article shall control and shall be deemed to supplement or amend the inconsistent provisions.*

##### **Hours of Trading**

*Rule 1. The E-Session shall be conducted on the Floor of the Exchange, commencing immediately following the close of the Post Primary Trading Session (the "PPTS") and ending at 5:30 P.M. Central time, Monday through Friday; provided, however, that no E-Session will be conducted, or a*

*shortened E-Session will be conducted, on those days identified by the Board of Governors, in its discretion, from time to time. So long as the rules in this Article remain in effect, the Secondary Trading Session shall be discontinued.*

##### **Eligible Securities**

*Rule 2. Securities eligible for trading during the E-Session ("E-Session Eligible Securities") shall be selected, from time to time, by the Committee on Floor Procedure from the securities eligible for trading during the PTS.*

##### **E-Orders**

*Rule 3. Orders eligible to be entered in the E-Session on a given day ("E-Orders") shall consist of those orders received by the Exchange on that day that are designated as E-Orders in the manner specified by the Exchange. All E-Orders transmitted via MAX shall include the account type designators in Article XX, Rule 37(b)(9).*

##### **Unexecuted Orders**

*Rule 4. All E-Orders for E-Session Eligible Securities remaining unexecuted at the end of an E-Session shall automatically be canceled.*

##### **Specialist Firms**

*Rule 5. The specialist firm for a security traded in the E-Session shall be the specialist firm assigned to that same security in the PTS, unless that specialist firm, with the approval of the Committee on Specialist Assignment and Evaluation, has transferred the assignment to another specialist firm for purposes of the E-Session only. A specialist firm assigned to one or more securities in the E-Session may cease acting in that capacity only with the permission of the Committee on Specialist Assignment and Evaluation.*

##### **Co-Specialists**

*Rule 6. A specialist firm may designate any qualified co-specialists in its assigned securities for the E-Session, whether or not they are co-specialists for those same securities during the PTS. A co-specialist must maintain a continuous, two-sided market in each assigned security.*

##### **Preopening Orders**

*Rule 7. Preopening orders in all E-Session Eligible Securities will be eligible for a single price opening.*

##### **Manner of Making Bids and Offers**

*Rule 8. The only orders eligible to be entered during the E-Session are unconditional limit orders for E-Session Eligible Securities. These orders shall be electronically and directly transmitted,*

*via MAX, to the specialist's limit order book; except that Floor Brokers (1) may route limit orders via MAX to the specialist's limit order book or, where permissible, transmit them to another market; or (2) may, after receiving a limit order to buy and a limit order to sell an equivalent amount of the same security (a) execute the orders at the specialist's post pursuant to Article XX, Rule 23 or (b) route the orders via MAX to the specialist's limit order book. NASDAQ System market makers, acting in their capacities as market makers, shall have direct telephone access to the specialist post in each NASDAQ/NM Security in which that market maker is registered as market maker to transmit orders for execution on the Exchange.*

##### **Specialist's Books**

*Rule 9. The book of limit orders entered for execution in the E-Session shall be maintained by the specialist in the E-Session and shall be separate from the specialist's books of limit orders maintained for that same security in the PTS and the PPTS.*

##### **Trading Halts Due to Extraordinary Market Volatility**

*Rule 10. If trading in all securities on the Exchange is halted during the PTS pursuant to Article IX, Rule 10A, and such halt is still in effect at the close of the PTS, the Exchange shall cancel the E-Session scheduled for that day. Two floor officials may halt trading in any or all securities during an E-Session if they determine that such action is necessary to preserve a fair and orderly market. Once trading in a given security is halted, two floor officials may reopen trading in the halted security if they determine that a fair and orderly market shall ensue from such action.*

##### **Intermarket Trading System**

*Rule 11. The Intermarket Trading System ("ITS") shall be in operation any time during the E-Session when another participant market is open for trading.*

##### **Customer Disclosure**

*Rule 12. No member or member organization may accept an order from a non-member for execution in the E-Session without first disclosing to that non-member that: (1) orders for E-Session Eligible Securities are eligible only for a single E-Session and, if not executed during that E-Session, shall automatically be canceled; (2) unconditional limit orders are the only orders that are eligible for execution in the E-Session; (3) there is likely to be less liquidity during trading that occurs once normal trading hours have ended and, as a consequence, there may be*

Commission approval, its proposed extended trading session will not be operational until October 29, 1999.

*greater fluctuations in securities prices; and (4) distinct systems and facilities trade securities after normal trading hours have ended and, as a consequence, at any particular time, quotations and transaction prices for a security may vary among those systems.*

#### Article IX—Trading Rules

\* \* \* \* \*

##### Business Days and Hours of Trading

\* \* \* \* \*

Rule 10(b) The Exchange will be open for business for three trading sessions during each business day.

The first trading session (the "Primary Trading Session") will be conducted on the floor of the Exchange (i) during the same hours the security is traded on its primary market, if the Exchange is not the primary market for such security, provided, however, if the primary market for such security is the Pacific Stock Exchange, the Primary Trading Session for that security shall end no later than 3 P.M. [p.m.] Central time, or (ii) from 8:30 A.M. to 3 P.M. Central time, Monday through Friday, if the Exchange is the primary market for such security. Notwithstanding the foregoing, trading in the Chicago Basket shall be conducted on the floor of the Exchange from 8:30 A.M. to 3:15 P.M., Central time, Monday through Friday.

The next trading session (the "Post Primary Trading Session") will be conducted on the floor of the Exchange for orders and securities designated as eligible for the Post Primary Trading Session, pursuant to Article XX, Rule 37. The Post Primary Trading Session shall be one-half hour after the close of regular trading on the primary market. In the event that trading on the Exchange is halted during the Primary Trading Session pursuant to Article XX, Rule 10A, and such halt is still in effect at the close of a Primary Trading Session, the Exchange will cancel the Post Primary Trading Session scheduled for that day.

The last session *the "E-Session"* shall be conducted on the floor of the Exchange, commencing immediately following the close of the Post Primary Trading Session and ending at 5:30 P.M., Central time, Monday through Friday; provided, however, that no E-Session will be conducted, or a shortened E-Session will be conducted, on those days identified by the Board of Governors, in its discretion, from time to time.

So long as the E-Session is being held, [(the ["Secondary Trading Session,"])] which was [will be] conducted through the Portfolio Trading System, pursuant to the provisions of Article XXXV from

3:30 P.M. to 5 P.M., Central time, Monday through Friday, will be discontinued. [The Floor of the Exchange shall be closed during the Secondary Trading Session.]

In the event of a crisis, the chairman or the vice-chairman of the Board of Governors or the president may, with the prior approval of a governor from a member firm and a governor from the floor, suspend trading at any time during a session.

#### Article XX—Regular Trading Sessions Application

Rule 1. These Rules shall apply to all Exchange Contracts made on the Exchange during the Primary Trading Session, [and] the Post Primary Trading Session and *the E-Session* and, to the extent determined by the Exchange to be applicable, to Exchange Contracts not made on the Exchange.

\* \* \* \* \*

##### Hours of Floor Dealings

Rule 2. Except as provided in Article XX, no member or member organization shall make any bid, offer or transaction upon the Floor of the Exchange, issue a commitment to trade through ITS from the Floor, or send an order in a Nasdaq/NM Security for execution via telephone to a NASDAQ System market maker other than during the Primary Trading Session, [or] the Post Primary Trading Session *or the E-Session*, except that a specialist may issue and receive pre-opening notifications and pre-opening responses, pursuant to the provisions of the Plan relating to the Pre-Opening Application of the System, before the official opening of business of the Exchange and loans of money or securities may be made after those hours.

\* \* \* \* \*

##### Guaranteed Execution System and Midwest Automated Execution System

Rule 37.(a) Guaranteed Executions. The Exchange's Guaranteed Execution System (the BEST System) shall be available, *during the Primary Trading Session and the Post Primary Trading Session*, to Exchange member firms and, where applicable, to members of a participating exchange who send orders to the Floor through a linkage pursuant to Rule 39 of this Article, in all issues in the specialist system which are traded in the Dual Trading System and NASDAQ/NM Securities.

\* \* \* \* \*

#### Article XXI—Exchange of Contracts, Tickets and Comparisons Reporting of Transactions

Rule 1. The Exchange shall report all transactions executed on the Floor during the Primary Trading Session, Post Primary Trading Session, *the E-Session* or , *when it is in operation*, through the Portfolio Trading System. It shall be the duty of every member to advise the Exchange of each of his transactions as promptly as possible.

#### Article XXXI—Odd Lots and Odd-Lot Dealers, Dual System

\* \* \* \* \*

##### Dealer Required To Purchase All Odd Lots Offered

Rule 6. In any security in which he or it is registered as such, an odd-lot dealer shall be required, *during the Primary Trading Session and the Post Primary Trading Session*, to purchase all odd lots offered him or it by any member or member organization of the Exchange and he or it shall be required to sell to any member or member organization of the Exchange any odd lots bid for by such member or member organization.

##### Execution of Odd-Lot Orders During the Primary Trading Session

Rule 9.(a) Exclusive Issues. \* \* \*

\* \* \* \* \*

##### Execution of Odd-Lot Orders During the E-Session

Rule 9a. *During the E-Session, odd lot orders shall be handled according to the requirements of Article XXA, Rule 8.*

#### Article XXXIV—Registered Market Makers—Equity Floor

Rule 1. A registered market maker shall only participate in transactions, while on the trading floor, during the Primary Trading Session and Post Primary Trading Session. A registered market maker shall effect all of his transactions in securities traded on the Exchange so that they constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market. No registered market maker shall enter into transactions or make bids or offers that are inconsistent with such a course of dealings.

\* \* \* \* \*

#### II. Self-Regulatory Organizations's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the

proposed rule change and discussed any comments it received regarding the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The CHX has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

**1. Purpose**

The Exchange is proposing to add new Article XXA and to amend several related rules, as detailed above, to implement an extended hours trading session. According to the Exchange, market participants and CHX members are demanding that the Exchange begin trading in hours that extend beyond the current trading day. The Exchange believes that after-hours trading may well become a permanent feature of the U.S. securities market and believes that investors will be best served if exchanges are participants in that market.

*The operation of the E-Session.* The E-Session extended trading hours session will be held from 3:30 p.m. (immediately following the close of the CHX's post primary trading session) to 5:30 p.m., Central time, Monday through Friday.<sup>5</sup>

Trading during the E-Session will be conducted, in some respects, as it is during the CHX's primary trading session; however, the Exchange has added new features to more fully automate the transmission of orders and to provide additional protections to investors who trade during the E-Session. Only unconditional limit orders will be eligible for execution in the E-Session and each limit order must be appropriately designated for trading in the E-Session. Any orders remaining unexecuted at the end of the E-Session will be automatically canceled and will not carry over to any other trading session. Specialist firms will continue to make two-sided, continuous markets in the stocks assigned to them during the existing trading sessions at their posts on the floor of the CHS, unless a specialist firm has transferred its assignment, for the E-Session only, to another specialist firm with the approval of the CHX's Committee on Specialist Assignment and Evaluation ("CSAE").

<sup>5</sup> See proposed amendments to Article IX, Rule 10(b) (Business Days and Hours of Trading) and Article XX, Rule 2 (Hours of Floor Dealing).

During the E-Session, in most cases, limit orders must be electronically and directly transmitted, via the MAX<sup>TM</sup> electronic order routing system, to the specialist's limit order book.<sup>6</sup> Floor brokers may route limit orders to the specialist's limit order book via MAX or may transmit the orders to another market. In addition, a floor broker may route orders to buy and sell equivalent quantities of the same security eligible to be executed at the same price through MAX to the specialist's limit order book or may execute those orders as a crossing transaction at the specialist's post in accordance with existing Exchange rules.

Except as described in Article XXA or in the rules amended as part of this submission, execution, reporting, and clearance and settlement of transactions that occur during the E-Session will follow the procedures currently in place for those activities in the Exchange's primary trading session.<sup>7</sup> Among other things, the National Securities Clearing Corporation ("NSCC") will clear the transaction that take place during this session<sup>8</sup> and the Securities Industry Automation Corporation ("SIAC") and Nasdaq, Inc. will disseminate CHX quotations and trade data.

The Exchange, however, proposes three changes to existing rules that arise from either the Exchange's desire to more fully automate the E-Session or from the fact that no primary market will be immediately available during the E-Session. First, the CHX's Guaranteed Execution System (the "Best System") and the automatic execution features of the Midwest Automated Execution System will not operate during the E-Session. In general, the Best System requires specialists to accept and execute orders at prices keyed to the primary market in each security. The

<sup>6</sup> Preopening orders in all E-Session Eligible Securities will be eligible for a single price opening. See proposed Article XXA, Rule 7. The single price to be applied to preopening orders will be determined based on the preopening limit orders represented on the limit order book at that time. In the event that there are no preopening limit orders represented on the limit order book at that time. In the event that there are no preopening limit orders on the book, the specialist will determine the opening price based on the closing price of the primary trading session. Telephone conversation between Paul O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, and Deborah Flynn, Special Counsel, Division, Commission, on October 13, 1999.

<sup>7</sup> See proposed amendments to Article XX, Rule 1 (Application) and Article XXI, Rule 1 (Reporting of Transaction).

<sup>8</sup> Transactions that take place during the E-Session will be reported to NSCC as part of the same end-of-day transmissions used for transactions conducted during the regular trading session. As a result, these transactions will be reported as same-day trades and will be subject to the normal three-day ("T+3") settlement cycle.

primary market likely will not be immediately available during the E-Session. The second change required by the E-Session relates to the execution of odd-lot orders. Current CHX rules require odd-lot dealers to execute all odd-lot orders from members and member organizations and require executive of all odd-lot orders (from members and others) at certain prices keyed to transactions on the primary market. Like the rules relating to the Best System, these rules will apply during the E-Session because of the likely absence of a primary market similar to the one that exists during normal trading hours. Finally, current Exchange rules permit market makers to operate during the primary trading session. Because market makers will not have access to MAX terminals, and therefore cannot route order to the specialists' limit order books during the E-Session, market makers will not participate in the E-Session from other trading floor. The amendments to Article XX, Rule 37 (relating to the Best System), Article XXXI, Rules 6 and 9 (Relating to odd-lot order execution) and Article XXXIV (relating to market makers) reflect these changes.

*Securities eligible for trading during the E-Session.* The CHX's Committee on Floor Procedure will identify, from time to time, the securities eligible for trading during the E-Session. At its meeting on September 21, 1999, the Committee on Floor Procedure adopted the list of potentially eligible securities recommended to it by the Exchange's New Product Development Committee. The 311 securities approved by the Committee on Floor Procedure include the securities listed on the Standard & Poor's ("S&P") 100 Stock Index<sup>TM</sup> ("OEX") as of August 30, 1999, the securities listed on the Nasdaq-100 Index<sup>®</sup> ("NDX") as August 30, 1999, and any other securities that ranked among the 100 most active listed and 100 most active New York Stock Exchange ("NYSE") or Nasdaq/NMS securities, and certain S&P Midcap and S&P 9 Select SPDRs securities as of the end of the second quarter of 1999.<sup>9</sup>

*Members eligible to participate in the E-Session.* All CHX members will access to the E-Session, in accordance with applicable CHX rules.<sup>10</sup>

<sup>9</sup> Telephone conversation between Paul O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, and Deborah Flynn, Special Counsel, Division, Commission, on October 7, 1999.

<sup>10</sup> Under a rule recently proposed by the CHX, if approved by the Commission, CHX members would be able to lease certain E-Session trading privileges to others, so long as the lessees are approved as members of the Exchange and meet other

*Trading halts due to extraordinary market volatility.* If trading in all securities on the CHX is halted during the primary trading session and the halt remains in effect at the close of that session, the Exchange will cancel the E-Session for that day. Two CHX floor officials can halt trading in any or all securities during and E-Session if they determine that such action is necessary to preserve a fair and orderly market, and two floor officials may reopen trading in any halted security on the same basis.

*Mandatory disclosures to non-members.* Because the E-Session operates in a manner, and at a time, that is different from the CHX's primary trading session, the proposal requires members to provide specific disclosures to non-members before accepting orders for execution in the E-Session. Specifically, a member cannot accept an order from a non-member before first disclosing that: (1) Orders for E-Session Eligible securities are eligible only for a single E-Session and, if not executed during that E-Session, shall automatically be canceled; (2) unconditional limit orders are the only orders that are eligible for execution in the E-Session; (3) there is likely to be less liquidity during trading that occurs once normal trading hours have ended and, as a consequence, there may be greater fluctuations in securities prices; and (4) distinct systems and facilities trade securities after normal trading hours have ended and, as a consequence, at any particular time, quotations and transaction prices for a security may vary among those systems. These disclosures are designed to ensure that participants in the after-hours market understand the potential risks of that participation.

*Surveillance and oversight.* The Exchange will surveil E-Session trading using enhanced surveillance programs.<sup>11</sup> E-Session order delivery, quoting and matching will be almost entirely controlled by the Exchange's electronic systems. These systems should reduce the possibility for intentional or inadvertent mishandling of orders and will enhance the effectiveness of the surveillance programs.

*Procedures for reviewing capacity, security and contingency planning.* The

CHX plans to use many of the same review procedures for systems security, capacity management, and recovery and contingency planning that it employs for the systems that support the primary trading session.

## 2. Statutory Basis

The CHX believes that the proposed rule change is consistent with Section 6(b)(5) of the Act<sup>12</sup> in that it is designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

### *B. Self-Regulatory Organization's Statement of Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition. Indeed, the Exchange believes that the proposed rule change will foster competition in the after-hours market.

### *C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Change Received From Members, Participants or Others*

No written comments were either solicited or received.

## III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filings will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR-CHR-99-16 and should be submitted by November 10, 1999.

<sup>12</sup> 15 U.S.C. 78f(b)(5).

## IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission has reviewed carefully the CHX's proposed rule change and believes, for the reasons set forth below, that the proposal is consistent with the requirements of Section 6 of the Act<sup>13</sup> and the rules and regulations thereunder applicable to a national securities exchange.<sup>14</sup> Specifically, the Commission believes that, by providing retail investors with an additional means to trade after regular trading hours, the proposal is consistent with Section 6(b)(5) of the Act<sup>15</sup> in that it is designed to remove impediments to, and to perfect the mechanism of, a free and open market. The implementation of the CHX's E-Session should enhance competition in the after-hours market. Currently, several electronic trading systems provide retail investors the opportunity to trade after-hours. The presence of a national securities exchange in the after-hours market should provide retail investors with an alternative forum through which to conduct after-hours transactions.

The Commission also believes that the rules and regulations applicable to Exchange members should enhance the transparency and integrity of the after-hours market and promote the goals of the national market system. Specifically, the Commission finds that the proposed rule change is consistent with Section 11A(a)(1)(C) of the Act.<sup>16</sup> Congress found in those provisions 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, and to assure the practicability of brokers executing investors' orders in the best market.<sup>17</sup> The proposed rule change accomplishes the objectives of the Act by ensuring that Nasdaq and SIAC systems, which are used by market participants to communicate quotations and transactions, will be available to investors outside of traditional market hours, thereby providing for greater transparency in the after-hours market.

In addition, the Commission notes that the CHX has added new features to

<sup>13</sup> 15 U.S.C. 78f.

<sup>14</sup> In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. <sup>15</sup> U.S.C. 78c(f).

<sup>15</sup> 15 U.S.C. 78f(b)(5).

<sup>16</sup> 15 U.S.C. 78k-1(a)(1)(C).

<sup>17</sup> *Id.*

requirements. See Securities Exchange At Release No. 41968 (September 30, 1999), 64 FR 54701 (October 7, 1999) (noticing File No. SR-CHX-99-08).

<sup>11</sup> Letters to Belinda Blaine, Associate Director, Division, Commission, from Paul B. O'Kelly, Executive Vice President, Market Regulation and Legal, CHX, dated October 6, 1999 and October 7, 1999.

more fully automate the transmission of orders and to provide additional protections to investors who trade during the E-Session. For example, only unconditional limit orders will be eligible for execution in the proposed E-Session and all such orders must be specifically designated as E-Session orders. E-Session orders that are not executed during the E-Session will be automatically canceled and are not carried over to the next-day primary session. The Commission further notes that the CHX proposes to require its members to provide certain disclosures to non-members about the proposed E-Session. The Commission believes that the CHX's proposed mandatory disclosures to non-members should ensure that customers are reasonably informed about the specific risks associated with participation in the after-hours market before their orders are accepted by a CHX member. These requirements are designed to limit, to the extent possible, the likelihood of investor confusion regarding the significant differences between the E-Session and the existing trading sessions. Moreover, the proposed requirement that specialist firms continue to make two-sided, continuous markets in the securities assigned to them for the existing trading sessions may provide further liquidity for investor orders.

In the Commission's view, the CHX's proposal to require its members to follow the rules and procedures currently in place for the existing trading session, with certain exceptions, is reasonable. The Commission notes that proposed exceptions result from the CHX's desire to more fully automate its E-Session and the fact that no primary markets are expected to be operating in the after-hours market at the time the CHX's E-Session is implemented. Although the Commission believes that the proposed exceptions are reasonable at this time, the Commission expects that the CHX's Best System and its existing rules governing odd-lot orders would be applied by the CHX to the E-Session as soon as the primary markets initiate trading in the after-hours market.<sup>18</sup>

The Commission further notes that the CHX has represented that it intends to implement enhanced surveillance procedure with respect to the proposed E-Session.<sup>19</sup> The enhanced surveillance capabilities should assist the CHX in satisfying the requirements of Section

6(b)(5) of the Act<sup>20</sup> that Exchange proposals be designed to promote just and equitable principles of trade.

Finally, the CHX has requested that the Commission find good cause pursuant to Section 19(b)(2) of the Act<sup>21</sup> for approving the proposed rule change prior to the 30th day after publication in the **Federal Register**. The Commission finds good cause for approving the proposed rule change prior to the 30th day after the date of publication of notice of filing thereof in the **Federal Register** because accelerated approval will benefit investors by providing retail investors with another venue, in this case, a national securities exchange, for executing transactions after regular trading hours. Moreover, the rules and regulations applicable to Exchange members should increase competition in, and enhance the transparency of, the after-hours market. In particular, SIAC and Nasdaq will disseminate CHX quotations and trade data on a real-time basis over the consolidated tape.

The Commission further believes that good cause exists for approving Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication in the **Federal Register**. The Commission notes that Amendment No. 1 merely establishes the extended hours trading session as a pilot program, scheduled to expire on March 1, 2000. The Commission believes that designation the E-Session as a pilot program will provide the Commission and the CHX with additional time to evaluate the issues implicated by after-hours trading. In addition, a pilot program should provide the Commission and the CHX with greater flexibility to modify the program to ensure consistency across markets when the primary markets extend their trading hours.

The Commission believes that good cause also exists to accelerate approval of Amendment No. 2 to the proposed rule change. Amendment No. 2 delays the date on which the proposal becomes operative to October 29, 1999 to provide the Exchange additional time to ensure that its systems are ready. The Commission believes that it is prudent for the CHX to take the requisite time to ensure that its systems are fully prepared prior to implementing its proposed E-Session. The Commission finds, therefore, that granting accelerated approval of the proposed rule change, including Amendment Nos. 1 and 2, is appropriate and consistent with Section 6 of the Act.<sup>22</sup>

## V. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>23</sup> that the proposed rule change (SR-CHX-99-16), as amended, is hereby approved on an accelerated basis as a pilot program, through March 1, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>24</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42001; File No. SR-CHX-99-17]

### Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Stock Exchange, Inc. Relating to Voluntary Delisting Requirements

October 13, 1999.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on September 24, 1999, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 proposes to amend Article XXVIII, Rule 4 of the Exchange's rules to modify the prerequisites to voluntary delisting from the Exchange. Specifically, the proposed rule change would delete the requirement that an issuer seeking to delist first obtain shareholder approval, replacing the deleted provisions with a provision requiring that the issuer first file with the Exchange a certified copy of its board resolution authorizing delisting.

<sup>23</sup> 15 U.S.C. 78s(b)(2).

<sup>24</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>18</sup> These changes would require the CHX to submit a rule filing with the Commission pursuant to Section 19(b) of the Act. 15 U.S.C. 78s(b).

<sup>19</sup> See *supra* note 11.

<sup>20</sup> 15 U.S.C. 78f(b)(5).

<sup>21</sup> 15 U.S.C. 78s(b)(2).

<sup>22</sup> 15 U.S.C. 78f.

## 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 self-regulatory organization 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 self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange has proposed the rule change in order to ensure that CHX-listed companies are not subject to more stringent voluntary delisting requirements than those imposed by other exchanges. In prior years, many exchanges included in their listing standards the requirement that an issuer seeking to delist voluntarily first obtain shareholder approval. Over time, this requirement has been deleted by each exchange (other than the CHX) and generally has been replaced with the requirement that the issuer demonstrate that its board of directors has authorized delisting. See, e.g., Amex Rule 18; PCX Rule 3.4(b); Phlx Rule 809.

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) <sup>3</sup> of the Act, in general, and section 6(b)(5) <sup>4</sup> of the Act, in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to, and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect 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 will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

## III. Date of Effectiveness of the Proposed Rule change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, located at the above address. Copies of such filing will also be available for inspection and copying at the principal office of the self-regulatory organization. All submissions should refer to File No. SR-CHX-99-17 and should be submitted by November 10, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>5</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42003; File No. SR-NASD-99-57]

### Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment No. 1 by National Association of Securities Dealers, Inc. Relating to the Extension of Certain Nasdaq Services and Facilities Until 6:30 p.m. Eastern Time

October 13, 1999.

Pursuant to Section 19(b)(1) of the Securities Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on October 5, 1999, the National Association of Securities Dealers, Inc. ("NASD"), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. On October 13, 1999, Nasdaq submitted Amendment No. 1 to the proposed rule change.<sup>3</sup> The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. For the reasons discussed below, the Commission is granting accelerated approval of the proposed rule change and Amendment No. 1 on a pilot basis through March 1, 2000.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,<sup>4</sup> Nasdaq is filing a proposed rule change to establish a pilot program extending the availability of several Nasdaq services and facilities until 6:30 p.m. Eastern Time. In addition, Nasdaq is proposing to extend the applicability of NASD Interpretive Material 2110-2 (the "Manning Rule") until 6:30 p.m. Eastern Time. Below is the text of the proposed rule change.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> Letter to Belinda Blaine, Associate Director, Division of Market Regulation ("Division"), Commission, from Thomas P. Moran, Assistant General Counsel, Nasdaq, dated October 12, 1999 ("Amendment No. 1"). In Amendment No. 1, Nasdaq proposes to amend the initial filing to request that the Commission approve its proposed extended hours trading session on a pilot basis beginning on October 25, 1999, through March 1, 2000. Nasdaq also explains in Amendment No. 1 how certain concerns regarding calculation of a 4 p.m. closing price will be addressed and how the Manning Rule will apply.

<sup>4</sup> 15 U.S.C. 78s(b)(1).

<sup>3</sup> 15 U.S.C. 78f(b).

<sup>4</sup> 15 U.S.C. 78f(b)(5).

<sup>5</sup> 17 CFR 200.30-3(a)(12).

Proposed new language is italicized;  
proposed deletions are in brackets.

\* \* \* \* \*

## IM-2110-2. Trading Ahead of Customer Limit Order

### (a) General Application<sup>5</sup>

To continue to ensure investor protection and enhance market quality, the Association's Board of Governors is issuing an interpretation to the Rules of the Association dealing with member firms' treatment of their customer limit orders in Nasdaq securities. This interpretation, *which is applicable from 9:30 a.m. to 6:30 p.m. Eastern Time*, will require members acting as market makers to handle their customer limit orders with all due care so that market makers do not "trade ahead" of those limit orders. Thus, members acting as market makers that handle customer limit orders, whether received from their own customers or from another member, are prohibited from trading at prices equal or superior to that of the limit order without executing the limit order. [provided that, prior to September 1, 1995, this prohibition shall not apply to customer limit orders that a member firm receives from another member firm and that are greater than 1,000 shares.] Such orders shall be protected from executions at prices that are superior but not equal to that of the limit order. In the interests of investor protection, the Association is eliminating the so-called disclosure "safe harbor" previously established for members that fully disclosed to their customers the practice of trading ahead of a customer limit order by a market-making firm.<sup>1</sup>

<sup>1</sup> "For purposes of the pilot program expanding the operation of certain Nasdaq transaction and quotation reporting systems and facilities in SR-NASD-99-57 during the period from 4 p.m. to 6:30 p.m. Eastern Time, members may generally limit the life of a customer limit order to the period of 9:30 a.m. to 4 p.m. Eastern Time. If a customer does not formally assent ("opt-in") to processing of their limit order(s) during the extended hours period commencing after the normal close of the Nasdaq market, limit order protection will not apply to that customer's order(s)."

\* \* \* \* \*

<sup>5</sup> On September 9, 1999, the NASD filed a proposed rule change (SR-NASD-99-44), which became effective upon filing pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(1) thereunder, modifying IM-2110-2 (exclusion of limit orders marketable at the time of receipt). A non-substantive amendment was filed on September 24, 1999. This filing incorporates the amendments filed in SR-NASD-99-44.

(b) Exclusion for Limit Orders That Are Marketable at Time of Receipt

No Change.

### 4617. Normal Business Hours

A Nasdaq market maker shall be open for business as of 9:30 a.m. Eastern Time and shall close no earlier than 4 p.m. Eastern Time. Should a market maker wish to *voluntarily* remain open for business later than 4 p.m. Eastern Time, it shall so notify the Nasdaq Market Operations via a Nasdaq terminal and shall close only on the hour or the half hour, but no later than 6:30 p.m. Eastern Time. *Nasdaq market makers whose quotes are open after 4 p.m. Eastern Time shall be obligated to comply, while their quotes are open, with all NASD Rules that are not by their express terms, or by an official interpretation of the Association, inapplicable to any part of the 4 p.m. to 6:30 p.m. Eastern Time period.*

### 4630. Reporting Transactions in Nasdaq National Market Securities

#### 4632. Transaction Reporting

(a) When and How Transactions Are Reported

(1)-(3) No Change.

(4) Transaction Reporting Outside Normal Market Hours. (A) Last sale reports of transactions in designated securities executed between 8 a.m. and 9:30 a.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution and shall be designated as ".T" trades to denote their execution outside normal market hours. Additionally, last sale reports of transactions in designated securities executed between the hours of 4 p.m. and [5:15] 6:30 p.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution; trades executed and reported after 4 p.m. Eastern Time shall be designated as ".T" trades to denote their execution outside normal market hours. Transactions not reported within 90 seconds must include the time of execution on the trade report.

(B) Last sale reports of transactions in designated securities executed outside the hours of 8 a.m. and [5:15] 6:30 p.m. Eastern Time shall be reported as follows:

(i) No Change.

(ii) Last sale reports of transactions executed between [5:15] 6:30 p.m. and midnight Eastern Time shall be transmitted through ACT on the next business day (T+1) between 8 a.m. and [5:15] 6:30 p.m. Eastern Time, be designated "as/of" trades to denote their execution on a prior day, and be accompanied by the time of execution. The party responsible for reporting on

T+1, the trade details to be reported, and the applicable procedures shall be governed, respectively, by paragraphs (b), (c), and (d) below.

(5)-(8) No Change.

### 4640. Reporting Transactions in Nasdaq Small Cap—Market Securities

#### 4642. Transaction Reporting

(a) When and How Transactions Are Reported

(1)-(3) No Change.

(4)(A) Last sale reports of transactions in designated securities executed between 8 a.m. and 9:30 a.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution and shall be designated as ".T" trades to denote their execution outside normal market hours. Additionally, last sale reports of transactions in designated securities executed between the hours of 4 p.m. and [5:15] 6:30 p.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution; trades executed and reported after 4 p.m. Eastern Time shall be designated as ".T" trades to denote their execution outside normal market hours. Transactions not reported within 90 seconds must include the time of execution on the trade report.

(B) Last sale reports of transactions executed outside the hours of 8 a.m. and [5:15] 6:30 p.m. Eastern Time shall be reported as follows:

(i) No Change.

(ii) Last sale reports of transactions executed between [5:15] 6:30 p.m. and midnight Eastern Time shall be transmitted through ACT on the next business day (T+1) between 8 a.m. and [5:15] 6:30 p.m. Eastern Time, be designated "as/of" trades to denote their execution on a prior day, and be accompanied by the time of execution. The party responsible for reporting on T+1, the trade details to be reported, and the applicable procedures shall be governed, respectively, by paragraphs (b), (c), and (d) below.

(5)-(8) No Change.

### 4650. Reporting Transactions in Nasdaq Convertible Debt Securities

#### 4652. Transaction Reporting

(a) When and How Transactions Are Reported

(1)-(3) No Change.

(4) Transactions Reporting Outside Normal Market Hours. (A) Last sale reports of transactions in designated securities executed between 8 a.m. and 9:30 a.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution and shall be designated as ".T" trades to denote their



execution outside normal market hours. Additionally, last sale reports of transactions in designated securities executed between the hours of 4 p.m. and [5:15] 6:30 p.m. Eastern Time shall be transmitted through the ACT system within 90 seconds after execution; trades reported after 4 p.m. Eastern Time shall be designated as ".T" trades to denote their execution outside normal market hours. Transactions not reported within 90 seconds must include the time of execution on the trade report.

(B) Last sale reports of transactions in designated securities executed outside the hours of 8 a.m. and [5:15] 6:30 p.m. Eastern Time shall be reported as follows:

(i) No Change.

(ii) Last sale reports of transactions executed between [5:15] 6:30 p.m. and midnight Eastern Time shall be transmitted through ACT on the next business day (T+1) between 8 a.m. and [5:15] 6:30 p.m. Eastern Time, be designated "as/of" trades to denote their execution on a prior day, and be accompanied by the time of execution. The party responsible for reporting on T+1, the trade details to be reported, and the applicable procedures shall be governed, respectively, by paragraphs (b), (c), and (d) below.

(5)-(7) No Change.

## 6600. Reporting Transactions in Over-the-Counter Equity Securities

### 6620. Transaction Reporting

(a) When and How Transactions Are Reported

(1)-(2) No Change.

(3) Transaction Reporting Outside Normal Market Hours. (A) Last sale reports of transactions in OTC Equity Securities executed between 8 a.m. and 9:30 a.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution and shall be designated as ".T" trades to denote their execution outside normal market hours. Last sale reports of transactions in OTC Equity Securities executed between the hours of 4 p.m. and [5:15] 6:30 p.m. Eastern Time shall also be transmitted through ACT within 90 seconds after execution; trades executed and reported after 4 p.m. Eastern Time shall be designated as ".T" to denote their execution outside normal market hours. Transactions not reported within 90 seconds must include the time of execution on the trade report.

(B) Last sale reports of transactions in OTC Equity Securities executed outside the hours of 8 a.m. and [5:15] 6:30 p.m. Eastern Time shall be reported as follows:

(i) No Change.

(ii) Last sale reports of transactions in ADRs, Canadian issues, or domestic OTC Equity Securities that are executed between [5:15] 6:30 p.m. and midnight Eastern Time shall be transmitted through ACT on the next business day (T+1) between 8 a.m. and [5:15] 6:30 p.m. Eastern Time, be designated "as/of" trades to denote their execution on a prior day, and be accompanied by the time of execution. The party responsible for reporting on T+1, the trade details to be reported, and the applicable procedures shall be governed, respectively, by paragraphs (b), (c), and (d) below; and

(iii) No Change.

(4)-(6) No Change.

\* \* \* \* \*

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Trading securities outside of normal market hours is not a new phenomenon. Nasdaq presently makes available several systems until 5:15 p.m. Eastern Time to facilitate trading after the close of the Nasdaq market at 4 p.m. Eastern Time. Recently, however, several alternative trading systems have initiated their own after-hours trading sessions. As such, there are now several different market venues available for trading after 4:00 p.m. Eastern Time. Presently there is no facility available to aggregate the activity in these various markets, making it difficult for market participants to determine the best prices available. Furthermore, information regarding transactions executed on these different markets is currently not widely available to investors, depriving them and other market participants of full, verifiable information on which to base trading decisions.

To remedy this situation, Nasdaq is proposing to establish a pilot program to extend, effective October 25, 1999 through March 1, 2000, the availability of its trade reporting and quotation

dissemination facilities until 6:30 p.m. Eastern Time to encourage the collection and public dissemination of securities transactions taking place after the 4 p.m. close of the Nasdaq market. These facilities are presently available until 5:15 p.m. Eastern Time. At the outset, Nasdaq wishes to stress that the above proposals are made in response to requests from other market participants that wish to expand their trading activity in the hours after the regular close of the Nasdaq market. It is Nasdaq's view that the importance of bringing increased transparency in the form of more visible quotes and transaction reports to the time period after the Nasdaq market's close imposes an obligation on Nasdaq to make available these systems and services as quickly as possible. Nasdaq remains committed to working with the Commission and other primary markets to carefully evaluate the complex issues surrounding any future expansion of regular market trading hours. Under the pilot proposal, Nasdaq will extend to 6:30 p.m. Eastern Time the operating hours of the following services: (1) SelectNet Service ("SelectNet"); (2) Automated Confirmation Transaction Service ("ACT"); (3) Nasdaq Quotation Dissemination Service ("NQDS"); and (4) Nasdaq Trade Dissemination Service ("NTDS"). The posting of quotations and trading of securities by NASD members during the period of time after Nasdaq's normal market close and before 6:30 p.m. Eastern Time shall be voluntary.

Under the pilot, any Nasdaq market maker that chooses to post quotations and trade during the 4 p.m. to 6:30 p.m. Eastern Time period shall be obligated to post firm two-sided quotations when opening and making its market, but may enter or leave the market on the hour or half-hour up to 6:30 p.m. Eastern Time. NASD member firms that do not choose to open their market and instead send customer or proprietary orders to other market participants for display and/or execution (or that choose to hold those orders until the next day's regular trading session) will likewise not be obligated to post firm two-sided quotes.<sup>6</sup> Regardless of an NASD member's quotation activity, all transactions in Nasdaq National Market, SmallCap, Convertible Debt and over-the-counter equity securities executed between the hours 8 a.m. and 6:30 p.m. Eastern Time

<sup>6</sup> Nasdaq market makers that do not elect to open their quotes would still be obligated to trade report transactions during the 4 p.m. to 6:30 p.m. Eastern Time period consistent with current trade reporting rules applicable during regular market hours.

must be reported to ACT within 90 seconds.

Along with the expanded operating times of the above systems and services, Nasdaq also wishes to make clear to members which NASD Rules will be in force during the extended SelectNet and ACT sessions. Except as modified by this filing, only those rules that are limited by their express terms, or by an official interpretation of the Association, to a specific time period outside of the 4 p.m. to 6:30 p.m. Eastern Time period shall not be in force during the extended SelectNet/ACT/NQDS/NTDS sessions. Towards that end, Nasdaq is proposing to modify NASD rule 4617 (Normal Business Hours) to make clear to Nasdaq market makers who voluntarily open their markets after the close that, except as modified by this filing, they are obligated to conduct their business during the extended SelectNet/ACT/NQDS/NTDS sessions in conformity with all NASD Rules whose applicability is not limited to specific times outside the 4 p.m. to 6:30 p.m. Eastern Time period. In addition, Nasdaq's Board of Directors, at its meeting on October 6, 1999, approved a proposal to amend NASD IM-2110-2 (also known as the "Manning Rule") to extend its applicability until 6:30 p.m. Eastern Time. The Manning Rule prohibits an NASD member firm which is holding a customer limit order from trading from that member's market making proprietary account at a price that would satisfy the customer's limit order without executing that customer limit order. This interpretation previously applied only during regular Nasdaq market hours.<sup>7</sup>

NASD's Short Sale Rule,<sup>8</sup> however, will not initially be applicable beyond normal market hours. In NASD Notice to Members 94-68, the NASD limited the Short Sale Rule's applicability to normal market hours (9:30 a.m. to 4 p.m. Eastern Time). In addition, technological constraints currently prevent Nasdaq from calculating a best bid/offer during the period between 4 p.m. and 6:30 p.m. Eastern Time. As a result, Nasdaq cannot provide the last bid directional arrow that is relied on by market participants to remain in compliance with the rule. Nasdaq believes that it will be technologically possible to calculate and provide an inside quote for the extended SelectNet session by on or about December 6, 1999. During the interim, Nasdaq will evaluate after-the-close trading activity to determine whether an extension of the Short Sale Rule to the 4 p.m. to 6:30 p.m. Eastern Time period is appropriate. Prior to the provision of an inside quote,

NASD members will, however, continue to be required to make affirmative determinations that they will receive delivery of a security from their customers or that the member can borrow the security on behalf of the customer for delivery by settlement date before accepting short sale orders during the extended SelectNet and ACT sessions.<sup>9</sup>

Finally, given the importance of timely trade reporting for transparency purposes, Nasdaq's trade reporting rules for NMS, SmallCap, Convertible Debt, and over-the-counter equity securities (Rules 4632, 4642, 4652, 6620) will be modified to mandate 90 second ACT trade reporting for all transactions in these securities executed after Nasdaq's regular market close and before 6:30 p.m. Eastern Time. Nasdaq staff will continue to initiate trading halts<sup>10</sup> and adjudicate clearly erroneous trade disputes in the extended SelectNet and ACT sessions using the same standards and methods as employed during normal market hours.<sup>11</sup> Nasdaq's MarketWatch and NASD Regulation's Market Regulation Department will be staffed to provide oversight of trading and quotation activity up to 7 p.m. Eastern Time.

*Amendment No. 1.* Among other things, Nasdaq's Amendment No. 1 addresses issues concerning the dissemination of regular session closing price reports under the pilot program. Specifically, the Amendment confirms that systems operations until 6:30 p.m. Eastern Time will not interfere with the ability of investors to obtain 4 p.m. closing prices in Nasdaq securities. Closing prices are currently disseminated by vendors shortly after the 4 p.m. close even though the Nasdaq systems operate until 5:15 p.m. Eastern Time; systems operations until 6:30 p.m. Eastern Time will not change this practice. Trades effected after 4 p.m. Eastern Time will continue to be

designated as ".T" trades that do not affect closing price in the relevant security.

Amendment No. 1 also describes how Nasdaq will address issues involving the use of closing prices for NAV calculations by mutual funds. In particular, under the Nasdaq proposal, certain specialized closing price reports for non-OTC Bulletin Board and foreign ordinary issues, as well as some American Depositary Receipts ("ADRs"), will not be issued by Nasdaq in time to permit funds to report their NAVs to Nasdaq's Mutual Fund Quotation Service ("MFQS") by that system's 5:50 p.m. Eastern Time deadline. Accordingly, Nasdaq has indicated that it will post an electronic file with this closing price information on the OTC Bulletin Board web site between 5:20 p.m. and 5:40 p.m. Eastern Time (with an internal goal of posting by 5:30 p.m. Eastern Time).

In addition, some funds and vendors have raised general concerns about what they perceived to be lack of time to modify and test their systems before the planned introduction of inside quotations up to 6:30 p.m. Eastern Time. Amendment No. 1 indicates that, in response to these concerns, Nasdaq has pushed back the planned start-up date for distributing after-hours inside quotations from November 1 to December 6, 1999. While Nasdaq acknowledges that this later start-up date will not satisfy every concern raised by vendors and funds, Nasdaq believes that the delay until December 6 should provide sufficient time for essential systems modifications and testing. Nasdaq states that it will continue to work with vendors and the mutual fund industry on these issues.

Amendment No. 1 also clarifies how the Manning Rule will apply during the extended hours of the pilot from 4 p.m. to 6:30 p.m. Eastern Time. Nasdaq confirms in Amendment No. 1 that, on October 6, 1999, the Board of Directors of Nasdaq approved the expansion of the applicability of the Manning Rule to 6:30 p.m. Eastern Time. Nasdaq also clarifies the application of the Manning Rule after 4 p.m. Eastern Time by adding a footnote to IM-2100-2(a) discussing the handling of customer limit orders if the customer does not formally opt-in to processing limit orders during the extended hours period.

Based on the above, Nasdaq believes that the proposed rule changes are consistent with the provisions of Section 15A(b)(b) of the Act in that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of

<sup>9</sup> See NASD Rule 3370.

<sup>10</sup> Nasdaq notes that this trading halt authority will be limited to individual stocks only and will be undertaken in consultation with other primary markets operating after 4 p.m. Eastern Time. Market-wide trading halt rules currently in effect rely solely on percentage-based declines in the Dow Jones Industrial Average ("DJIA"), a narrow index that does not contain any Nasdaq stocks and which will not be calculated after the 4 p.m. close. In the event that a circuit breaker halt, triggered during regular market hours, prevents a normal close of U.S. primary markets, Nasdaq proposes that no extended SelectNet or ACT sessions be commenced that day.

<sup>11</sup> Nasdaq has also been informed by the staff of NASD Regulation, Inc. of its view that nothing in the instant proposals modifies or limits an NASD member's obligation to comply with the rules of NASD Regulation's Order Audit Trail System ("OATS") when reporting trading activity taking place between 4 p.m. and 6:30 p.m. Eastern Time. Nasdaq's MarketWatch and NASD Regulation's Market Regulation Department will be staffed to provide oversight of trading and quotation activity up to 7 p.m. Eastern Time.

<sup>7</sup> See NASD Notice to Members 95-67.

<sup>8</sup> NASD Rule 3350.

trade, and to foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in securities.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

#### *C. SRO's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Although written comments were not solicited, Nasdaq has received four letters from market participants expressing concerns relating to the proposed rule change.<sup>12</sup> Nasdaq has addressed these comment letters in Amendment No. 1.

### **III. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No.

<sup>12</sup> Letter to Richard G. Ketchum, President, NASD, from Craig S. Tyle, General Counsel, Investment Company Institute, dated September 24, 1999; Letter to Richard G. Ketchum, President, NASD, and Patrick J. Campbell, Chief Operating Officer and Executive Vice President, The Nasdaq-Amex Market Group, Inc., from Jenni Neumann, Senior Vice President, Global Database Management, Bridge Information Systems, dated September 27, 1999; Letter to Richard G. Ketchum, President, NASD, from David Byrnes, Senior Vice President, Americas Information Management Group, Reuters Information, dated September 28, 1999; and Letter to Richard G. Ketchum, President, NASD, from Thomas J. Higgins, Principal and Treasurer of the Vanguard Funds, The Vanguard Group, dated September 29, 1999.

SR-NASD-99-57 and should be submitted by November 10, 1999.

### **IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change**

For the reasons discussion below, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of Sections 11A and 15A.<sup>13</sup>

Specifically, the Commission believes that the proposed rule change as amended furthers the goals of the national market system as reflected in Sections 11A(a)(1)(C)(iii) and (iv) of the Act.<sup>14</sup> Congress found in those provisions 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, and to assure the practicability of brokers executing investors' orders in the best market. Section 11A(a)(1) further found that the linking of all markets for qualified securities through communication and data processing facilities would foster efficiency, enhance competition, increase the information available to brokers, dealers, and investors, facilitate the offsetting of investors' orders, and contribute to best execution of such orders.<sup>15</sup> The proposed rule change as amended will assure the availability of information with respect to quotations and transactions because it makes Nasdaq's systems, which are used by market participants to communicate quotes and orders and to report trades, available until 6:30 p.m. Eastern Time. Currently, there is not consolidated source of information on trades and quotations after 5:15 p.m. Eastern Time, making it difficult for investors to determine the best prices available. Nasdaq's proposal will enhance transparency by requiring that transactions in NMS, SmallCap, Convertible Debt, and over-the-counter equity securities that take place up to 6:30 p.m. Eastern Time be reported within 90 seconds. In addition, to the extent that a market maker chooses to participate in the after-hours session, its quotations will be disseminated through NQDS. As a result, investors will be

<sup>13</sup> In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>14</sup> 15 U.S.C. 78k-1(a)(1)(C) (iii) and (iv).

<sup>15</sup> 15 U.S.C. 78k-1(a).

better able to evaluate prices before entering their order after primary trading hours. In sum, by providing the consolidated quotation display and last sale tape for transactions taking place between 4 p.m. and 6:30 p.m. Eastern Time, Nasdaq's proposal should enhance investor protection and confidence because it will give market participants more complete information upon which to base trading decisions.

The Commission also believes that the proposed rule change is consistent with Section 15A of the Act<sup>16</sup> in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change accomplishes these objectives by making Nasdaq's systems available to market participants who choose to offer trading to customers outside of traditional market hours, by providing for greater transparency, and by linking the various market participants engaged in trading during those hours through SelectNet.

Amendment No. 1 also confirms that the extended trading pilot will not interfere with the ability of investors to obtain 4 p.m. closing prices in Nasdaq securities. Moreover, Nasdaq has outlined measures that it has taken to address specific concerns of vendors and the mutual fund industry concerning the availability of closing prices for NAV calculations and the need for sufficient time to modify and test their systems before the planned introduction of inside quotations after 4 p.m. Eastern Time. While Nasdaq acknowledges that these measures will not satisfy every concern raised by vendors and funds, the delay until December 6th for the dissemination of after-hours inside quotations should provide sufficient time for essential systems modifications and testing. Nasdaq has indicated that it will continue to work with vendors and the mutual fund industry on these issues. In light of the need for improved transparency during the after-hours session, and Nasdaq's willingness to continue to work with vendors and mutual funds to ensure an orderly extension of price reporting, the Commission believes that Nasdaq's

<sup>16</sup> 15 U.S.C. 78o-3.

determination to proceed with its pilot on schedule is reasonable.

In addition, the proposed rule change as amended furthers the objectives of Section 15A of the Act by specifically extending rules designed to protect investors beyond the traditional market hours while Nasdaq's systems are operating. For example, the Manning Rule previously did not apply after 4 p.m. Eastern Time. Originally, the NASD believed Manning obligations should not apply after 4 p.m. Eastern Time because the after-hours market was fundamentally different from the regular market.<sup>17</sup> With the advent of on-line retail trading and other technological advances, however, the nature of the after-hours market is changing. In particular, the increasing presence of retail customers during the after-hours market has led the NASD to reconsider the application of the Manning Rule between 4 p.m. and 6:30 p.m. Eastern Time. Accordingly, upon approval of the pilot, members acting as market makers during these hours will be required to handle their customer limit orders with due care so that they do not trade ahead of those limit orders. Members acting as market makers that handle customer limit orders, whether received from their own customers or from another member, will be prohibited from trading at prices equal or superior to that of the limit order without executing the limit order. The Commission believes that the application of the protections of the Manning and other NASD rules during after-hours trading will significantly enhance investor protection.<sup>18</sup>

#### Commission Rules

The Commission has received inquiries from market participants seeking clarification regarding which Commission rules apply to NASD members who choose to trade after 4 p.m. Eastern Time while Nasdaq's systems are in operation. The Commission wishes to clarify that, by their terms, SEC Rules 11Ac1-1(c)(2) (the "Firm Quote Rule"), 11Ac1-1(c)(5) (the "ECN Display Alternative"), 11Ac1-4 (the "Limit Order Display Rule") and Rule 301(b) ("Regulation ATS") apply to NASD member firms

that choose to trade between 4 p.m. and 6:30 p.m. Eastern Time.<sup>19</sup>

In general, SEC Rule 11Ac1-1(b)(1)(ii) requires an association to disseminate the best bid, offer, and quotation sizes for subject securities whenever "last sale information with respect to reported securities is reported [by a member acting in the capacity of an OTC market maker] pursuant to an effective transaction reporting plan."<sup>20</sup> NASD members, including OTC market makers, who choose to trade from 4 p.m. to 6:30 p.m. Eastern Time will be required to report last sale information pursuant to the NASD's rules, and the NASD will disseminate quotes during this time period. These procedures, in turn, trigger the Commission's Firm Quote Rule, which generally obligates OTC market makers to execute any order to buy or sell a subject security, other than an odd-lot order, presented to it by another broker or dealer, or any other person belonging to a category of persons with whom such responsible broker or dealer customarily deals, at a price at least as favorable to such buyer or seller as the responsible broker's or dealer's published bid or published offer.

Similarly, the reporting of last sale information to the NASD triggers the ECN Display Alternative. Under the ECN Display Alternative, an order entered by a market maker into an electronic communications network ("ECN") that widely disseminates the order is deemed to be a bid or offer to be communicated to the market maker's association for at least the minimum quotation size required by the Association's rules if the priced order is for the account of the market maker, or the actual size of the order up to the minimum quotation size required if the priced order is for the account of a customer. The ECN Display Alternative deems the market maker to be in compliance with this requirement if the ECN displays the market maker's order in Nasdaq.<sup>21</sup>

In addition, the Limit Order Display Rule is not limited to regular trading hours, but also applies to OTC market makers that choose to participate in after-hours trading sessions. Simply put,

the Limit Order Display Rule requires an OTC market maker to publish immediately a bid or offer that reflects the price and full size of each customer limit order that improves the bid or offer of the OTC market maker, or that reflects the full size of the customer limit order that is priced equal to the bid or offer of the OTC market maker or the national best bid or offer, and represents more than a *de minimis* change in the size of the OTC market maker's bid or offer.<sup>22</sup>

Regulation ATS also applies to market participants who choose to operate from 4 p.m. to 6:30 p.m. Eastern Time. Currently, any alternative trading system that has five percent or more of the average daily trading volume in a security must display its best orders in that security in the public quotation stream during regular trading hours. Although there may be some confusion as to whether average "daily" trading volume includes trades executed outside of normal market hours, the calculation alternative trading systems must make regarding volume includes *all* trades executed during the twenty-four hours that constitute a day. Any alternative trading system that meets the five percent threshold must therefore display its orders in the public quotation stream whenever the public quotation systems make display possible.

The Commission is aware that there has been confusion among market participants as to the applicability of these rules after 4 p.m. Eastern Time. Consequently, the Commission has issued a no-action letter to the NASD relieving market participants from complying with Rules 11Ac1-1(c)(5) (the ECN Display Alternative), 11Ac1-4 (the Limit Order Display Rule), Rule 301(b) (Regulation ATS), and the NASD's Manning Rule until November 2, 1999.<sup>23</sup> This temporary relief is designed to give market participants (including ECNs) time to make the system changes necessary to comply with these rules during the 4 p.m. to 6:30 p.m. Eastern Time period.<sup>24</sup> The Commission emphasizes, however, that broker-dealers continue to have a duty of best execution for their customer's orders during these hours.

<sup>17</sup> See, e.g., NASD Notice to Members 95-67.

<sup>18</sup> The Commission believes that the clarification of the application of the Manning Rule in Amendment No. 1 provides further enhancement of investor protection. In addition, the Nasdaq staff has indicated that a rule proposal is being developed for consideration by the appropriate Boards that would require that member firms establish procedures to have customers "opt-in" to having their order(s) processed during any period outside of the 9:30 a.m. to 4 p.m. regular trading session for Nasdaq.

<sup>19</sup> 17 CFR 240.11Ac1-1(c)(2), 17 CFR 240.11Ac1-1(c)(5), 17 CFR 240.11Ac1-4, 17 CFR 242.301(b).

For a complete discussion of these rules and the definitions of the terms used in the following discussion, see the applicable Commission releases.

<sup>20</sup> 17 CFR 240.11Ac1-1(b)(1)(ii).

<sup>21</sup> Therefore, if an ECN is receiving OTC market maker orders before 6:30 p.m. Eastern Time, the ECN must transmit those orders through SelectNet for display in the Nasdaq montage, or the OTC market maker must post the quote separately in its own quote line in the montage in order to be in compliance with the ECN Display Alternative.

<sup>22</sup> There are certain exceptions to the Limit Order Display Rule. Those exceptions would continue to apply during an after-hours trading session. See SEC Rule 11Ac1-4(c), 17 CFR 240.11Ac1-4(c).

<sup>23</sup> Under the terms of this no-action letter, firms are not relieved from their obligation to comply with the Firm Quote Rule (Rule 11Ac1-1(c)(5), 17 CFR 240.11Ac1-1(c)(5)).

<sup>24</sup> See Letter to Robert E. Aber, General Counsel, Nasdaq, from Robert L.D. Colby, Deputy Director, Division, Commission, dated October 12, 1999.

Nasdaq has requested that the Commission find good cause pursuant to Section 19(b)(2) of the Act<sup>25</sup> for approving the proposed rule change prior to the 30th day after publication in the **Federal Register**. The Commission finds good cause for granting accelerated approval for the proposed rule change because the Nasdaq pilot will benefit investors by improving the transparency of the current after-hours market and assisting broker-dealers in fulfilling their duty of best execution for their customer orders.

The Commission further believes that good cause exists for approving Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. The first item covered in Amendment No. 1 merely changes the date for implementation of the after-hours trading session as a pilot program from October 11, 1999 to October 25, 1999. The Commission believes that delaying the implementation date will provide Nasdaq and its member firms with additional time to make any necessary systems changes. The second and third items of Amendment No. 1 address how the Manning Rule will apply during the extended hours of the pilot from 4 p.m. to 6:30 p.m. Eastern Time. In the second item, Nasdaq confirmed that, on October 6, 1999, the Board of Directors of Nasdaq approved the expansion of the applicability of the Manning Rule to 6:30 p.m. Eastern Time. In the third item, Nasdaq clarified the application of the Manning Rule after 4 p.m. Eastern Time by adding a footnote to IM-2110-2(a) discussing the handling of customer limit orders if the customer does not formally opt-in to processing limit orders during the extended-hours period. The Commission believes that the Manning Rule's customer limit order protections should be provided to customers who opt-in to having their orders processed in the extended-hours period, and that, therefore, there is good cause for accelerating the approval of these items in Amendment No. 1. The Commission notes that the remaining items discussed in Amendment No. 1 clarify how Nasdaq will continue to make certain trade information available to the mutual fund industry. These clarifications further ensure that the pilot program will provide protection to investors who participate in the market through mutual funds. Accordingly, the Commission believes that there is good cause for accelerating the approval of all of the items in Amendment No. 1.

While extended operation of some key Nasdaq trade reporting and quotation dissemination systems will significantly improve the current trading environment after the major markets close, the Commission recognizes that Nasdaq's pilot program does not yet include some features that would be essential for a full after-hours trading session. Specifically, Nasdaq's pilot does not require registered market makers in Nasdaq securities to participate in after-hours trading from 4 p.m. to 6:30 p.m. Eastern time and does not envision the use of the Small Order Execution System ("SOES") during this period. In Nasdaq's view, its market will not be open during the hours of the pilot. The Commission believes that, before Nasdaq opens its market for extended trading, it would need to incorporate additional market integrity and investor protection features.<sup>26</sup>

In addition, the Commission has expedited approval of this proposal with the understanding that the systems limitations that currently prevent the calculation of the best bid and offer for Nasdaq stocks after 4 p.m. Eastern Time will be addressed expeditiously. Such calculations will be necessary for the Nasdaq's Short Sale Rule to apply to trading during the 4:30 p.m. to 6:30 p.m. Eastern Time period. The Commission expects that Nasdaq will make every reasonable effort to work with the vendors and the mutual fund community to implement the systems enhancements needed for calculating the inside quote as soon as possible.

## V. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>27</sup> that the proposed rule change (SR-NASD-99-57), including Amendment No. 1, is approved as a pilot program through March 1, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>28</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc 99-27308 Filed 10-19-99; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-41996; File No. SR-NYSE-98-47]

### Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change and Amendment No. 1 and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 2 to Proposed Rule Change To Adopt Rule 440 I Requiring Records of Compensation Arrangements Concerning Floor Brokerage

October 8, 1999.

## I. Introduction

On December 23, 1998, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to adopt Rule 440 I, requiring records of compensation arrangements concerning floor brokerage. On May 14, 1999, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>3</sup>

The proposed rule change and Amendment No. 1 were published for comment in the **Federal Register** on June 2, 1999.<sup>4</sup> The Commission received no comments on the proposal. On June 23, 1999, the NYSE submitted Amendment No. 2 to the proposed rule change.<sup>5</sup> This notice and order approves the proposed rule change as amended and seeks comment from interested persons concerning Amendment No. 2.

## II. Description of the Proposal

Proposed Rule 440 I would require that every member not associated with a member organization, and each member organization primarily engaged as an agent in executing transactions on the Floor of the Exchange, maintain a

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Letter to Richard Strasser, Assistant Director, Division of Market Regulation ("Division"), SEC, from James E. Buck, Senior Vice President and Secretary, NYSE, dated May 12, 1999. In Amendment No. 1, the Exchange explained why the proposed rule change would apply only to floor members and member organizations but not to "upstairs" members and member organizations.

<sup>4</sup> Securities Exchange Act Release No. 41441 (May 24, 1999), 64 FR 29723.

<sup>5</sup> See Letter to Richard Strasser, Assistant Director, Division, SEC, from Daniel Parker Odell, Assistant Secretary, NYSE, dated June 22, 1999. In Amendment No. 2, the Exchange revised the proposed rule test in Supplementary Material .10(a) to exclude compensation arrangements involving gross compensation of less than \$5,000, rather than the originally proposed level of \$10,000.

<sup>25</sup> 15 U.S.C. 78s(b)(2).

<sup>26</sup> See, e.g., n. 18, *supra*.

<sup>27</sup> 15 U.S.C. 78s(b)(2).

<sup>28</sup> 17 CFR 200.30-3(a)(12).

written record of each type of compensation arrangement that they enter into with other members, member organizations, non-member organizations, or customers relating to transactions on the Floor. The written record would include a description of each type of arrangement and identify, by name, the parties to each type of arrangement in effect.

In addition, proposed Rule 440 I, Supplementary Material .10 would exclude the following compensation arrangements from the requirement to maintain a written record:

(1) Arrangements involving gross compensation of less than \$5,000 per year;<sup>6</sup> and

(2) Arrangements involving orders transmitted solely through the Exchange's electronic order routing system.<sup>7</sup>

Proposed Rule 440 I, Supplementary Material .20 would provide that a member or member organization is deemed to be primarily engaged as an agent in executing transactions on the Floor of the Exchange if at least 75% of its revenue is derived from floor brokerage.

The proposed would apply to members and member organizations primarily engaged as agents in executing transactions on the Floor of the Exchange. It would specify a type of record, records of compensation arrangements, in addition to the records required to be maintained under Exchange Act Rules 17a-3<sup>8</sup> and 17a-4,<sup>9</sup> that the Exchange believes is critical to providing the Exchange the ability to monitor floor broker activities. The proposed would not apply to "upstairs" (i.e., off the Floor) members and member organizations. The proposal explains that independent brokers do not generally have independent supervisory structures nor are they subject to the same formalized internal supervisory oversight as "upstairs" organizations because many independent brokers act as sole proprietors with a limited customer and product base.

### III. Discussion

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, and, in particular, with the requirements of Section 6(b).<sup>10</sup> Specifically, the Commission believes that by strengthening the Exchange's ability to examine and surveil activities on the Exchange Floor, the proposal is consistent with the Section 6(b)(5)<sup>11</sup> requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to 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.<sup>12</sup>

The proposed rule change is intended to fulfill some of the requirements of the undertakings contained in the order issued by the Commission relating to the settlement of an enforcement action against the NYSE for failure to enforce compliance with Section 11(a) and Rule 11a-1 of the Exchange Act and NYSE Rules 90, 95 and 111.<sup>3</sup> The SEC Order found that the NYSE's floor broker regulatory program suffered from two major deficiencies: (1) The NYSE failed to take appropriate action to police for profit-sharing or other performance-based compensation of independent floor brokers; and (2) the NYSE suspended its routine independent floor broker surveillance for extensive periods of time.<sup>14</sup> Pursuant to the SEC Order, among other things, the NYSE agreed and was ordered to enhance and improve by June 28, 2000 its regulation of independent floor brokers, member firm floor brokers, specialists, registered competitive market makers and competitive traders (collectively "Floor Members") by: (a) examining the floor trading activities of all floor members every two years; (b) ongoing, continuous surveillance of all floor members; (c) thoroughly investigating indications of possible violations by floor members; (d) ensuring that members of its regulatory staff are present on the NYSE trading floor during trading hours to surveil for potential trading violations; (e) ensuring adequate coordination among all staff responsible for floor

members surveillance, investigations, and disciplinary matters; and (f) increasing staff with adequate expertise in the regulations of floor members within the Department of Member Trading Analysis. The Commission believes that, by strengthening the Exchange's ability to examine and surveil independent floor brokers' activities on the Exchange Floor, the proposed rule change is consistent with and is an important step toward satisfying certain of the undertakings relating to floor broker oversight.

The proposal requires members and member organizations primarily engaged as agents in executing transactions on the Floor of the Exchange (i.e., firms where 75% of revenue is derived from floor brokerage) to maintain a detailed written record of their compensation agreements, unless the arrangement involves gross compensation of less than \$5,000 per year or involves orders transmitted solely through the Exchange's electronic order routing system. The Commission finds that requiring members and member organizations to maintain records of these compensation arrangements will facilitate the Exchange's review of such arrangements on an ongoing basis is part of the routine examination process, as well as on a for cause basis, for compliance with Section 11(a) of the Act<sup>15</sup> in terms of whether any such arrangement constitutes a member or member organization having an interest in an account. The Commission also finds that enhancing the recordkeeping requirement of this limited group of Exchange members with respect to compensation arrangements is consistent with the Exchange's responsibility, under Section 6(b)(5) of the Act, to prevent fraudulent and manipulative acts and practices.

The Exchange clarifies that the scope of the proposal encompasses "\$2 brokers" or "independent brokers" but excludes "upstairs" members and member organizations. The proposal explains that independent brokers do not generally have independent supervisory structures nor are they subject to the same formalized internal supervisory oversight as "upstairs" organizations because many independent brokers act as sole proprietors with a limited customer and product base. Requiring independent floor brokers to maintain records of

<sup>6</sup> *Id.*

<sup>7</sup> The NYSE is proposing to exclude orders transmitted solely through the Exchange's electronic order routing system because the Exchange believes the automatic feature of this system prevents manipulation by independent floor brokers. Telephone conversation between Mary Anne Furlong, Director, Rule and Interpretive Standards, NYSE, and Heather Traeger, Attorney, Division, SEC, on July 16, 1999.

<sup>8</sup> 17 CFR 240.18a-3.

<sup>9</sup> 17 CFR 240.18a-4.

<sup>10</sup> 15 U.S.C. 78f(b).

<sup>11</sup> 15 U.S.C. 78f(b)(5).

<sup>12</sup> In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>13</sup> See In the Matter of New York Stock Exchange, Inc., SEC Release No. 34-41574, June 29, 1999; Administrative Proceeding File No. 3-9925 ("SEC Order").

<sup>14</sup> *Id.*

<sup>15</sup> Subject to certain exemptions, Section 11(a) prohibits a member or member organization from executing on the Exchange an order for that member's or member organization's "own account" or any account in which the member or member organization has an interest. 15 U.S.C. 78k(a).

compensation arrangements will facilitate the Exchange's ability to monitor independent floor broker activities, which may lack the internal safeguards in place at upstairs firms.

The Commission finds good cause for approving Amendment No. 2 to proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. Amendment No. 2 revises the proposed rule text in Supplementary Material .10(a) to exclude compensation arrangements involving gross compensation of less than \$5,000, rather than the originally proposed level of \$10,000. The Commission believes that the change in the compensation threshold is consistent with proposed Rule 440 I's intent to help the Exchange surveil for potentially abusive compensation arrangements without adding an undue burden of those firms required to keep records under the proposed rule. Accordingly, the Commission finds that good cause exists, consistent with Section 6(b)(5) <sup>16</sup> and Section 19b(b)(2) of the Act,<sup>17</sup> to grant accelerated approval of Amendment No. 2.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 2, including whether Amendment No. 2 is consistent with the Act. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to File No. SR-NYSE-98-47 and should be submitted by November 10, 1999.

#### V. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>18</sup> that the

proposed change (SR-NYSE-98-47), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>19</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 99-27369 Filed 10-19-99; 8:45 am]

BILLING CODE 8010-01-M

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-41994; File No. SR-PCX-99-34]

#### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Market Maker Charges and Book Charges

October 8, 1999.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") <sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on August 27, 1999, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On September 28, 1999, the PCX submitted to the Commission Amendment No. 1 to the proposed rule change.<sup>3</sup> 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 PCX proposes to change its Schedule of Fees and Charges for Exchanges services by increasing Market Maker transaction charges and eliminating Book Execution, Book Staff Entry and Lead Market Maker ("LMM") Book Program Staffing charges. The text of the proposed rule change is attached as *Exhibit A* and is available at the Exchange and at the Commission.

<sup>19</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Letter from Robert Pacileo, Staff Attorney, Regulatory Affairs, PCX to Michael Walinskas, Associated Director, Division of Market Regulation, Commission, dated September 27, 1999 ("Amendment No. 1"). Amendment No. 1 clarifies the operation of the market maker and book charges affected by the proposed rule change. Because Amendment No. 1 is substantive the Commission deems the date of the filing to be September 28, 1999, the date the amendment was filed with the Commission.

#### 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 PCX proposes to make the following changes to its Schedule of Fees and Charges for PCX services:

a. *Market Maker Transaction Fee.* The PCX currently charges Market Makers a transaction fee of \$0.15 per contract side for equity and index options. The PCX proposes to increase this fee to \$0.185 per contract side to offset the loss in revenues anticipated to result from the proposed elimination of the fees set forth in "b," "c," and "d" below.

b. *Book Execution Fee.* The PCX charges executing brokers a Book Execution Fee of \$0.20 per contract side and an Accommodation/Liquidation Transaction Fee of \$0.10 per contract side.<sup>4</sup> The Book Execution Fee is assessed each time an order in the Book is executed; the Accommodation/Liquidation Fee is charged for so-called "cabinet" trades in which the premium is less than  $\frac{1}{16}$ .<sup>5</sup> The PCX proposes to eliminate its Book Execution and Accommodation/Liquidation Transaction Fees.

c. *Book Staff Entry Fee.* The PCX charges its executing brokers a Book Staff Entry Fee, applied to orders manually entered onto the Book by PCX staff, of \$0.50 per entry.<sup>6</sup> The PCX now proposes to eliminate this Fee.

<sup>4</sup> The executing broker may pass the fee on to its customer, or may absorb the fee itself, depending on the broker's contractual relationship with its customers. Telephone conversation between Robert Pacileo, Staff Attorney, Regulatory Affairs, PCX, and Gordon Fuller, Special Counsel, and Marla Chidsey, Law Clerk, Division of Market Regulation, Commission (October 7, 1999).

<sup>5</sup> Telephone conversation between Robert Pacileo, Staff Attorney, Regulatory Affairs, PCX, and Gordon Fuller, Special Counsel, and Marla Chidsey, Law Clerk, Division of Market Regulation, Commission (September 9, 1999).

<sup>6</sup> As with the Book Execution and Accommodation/Liquidation Fees discussed above, the executing broker may pass on the Book Staff Entry Fee to its customers. *Supra* note 4.

<sup>16</sup> 15 U.S.C. 78f(b)(5).

<sup>17</sup> 15 U.S.C. 78f(b)(1).

<sup>18</sup> 15 U.S.C. 78s(b)(2).



d. *LMM Book Program Staffing Charges.* The PCX charges its Lead Market Makers ("LMM") for options contracts entered into the Book. Each LMM is charged \$0.05 per Book contract for the first 15,000 contracts, \$0.10 for 15,001 to 30,000 Book contracts, \$0.15 for the 30,001 to 55,000 Book contracts, and \$0.10 for all Book contracts over 55,000. These charges are applied to the monthly total of all Book contracts in all options issues collectively traded by an LMM under the program. The PCX proposes to eliminate its Book Program Staffing Charges.

The PCX proposes these fee changes for several reasons. First, the PCX seeks to reduce charges consistent with the elimination of Book Execution and Book Staff Entry Fees currently paid by executing brokers.<sup>7</sup> Second, the elimination of Book Execution and Book Staff Entry Fees is intended to attract order flow to the PCX and make its rate schedule more competitive. Finally, the elimination of LMM Book Program Staffing Charges is consistent with the elimination of the Book Execution and Book Staff Entry Fees. PCX market makers will pay an increased transaction fee to enable PCX to recoup revenues lost through elimination of the three Book fees.<sup>8</sup>

## 2. Statutory Basis

The Exchange represents that the proposed rule change is consistent with Section 6(b) of the Act,<sup>9</sup> in general, and furthers the objectives of Section 6(b)(4),<sup>10</sup> in particular, because it provides for other equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange represents that it does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

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

The foregoing rule change has become immediately effective pursuant to Section 19(b)(3)(A) of the Act<sup>11</sup> and Rule 19b-4(f)(6) under the Act<sup>12</sup> because:

- (i) It does not significantly affect the protection of investors or the public interest;
- (ii) It does not impose any significant burden on competition; and
- (iii) By its terms, it does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest: provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

In this regard, the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days before the date of the filing, as required by Rule 19b-4(f)(6).<sup>13</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the proposed 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.<sup>14</sup>

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. 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

<sup>11</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>12</sup> 17 CFR 240.19b-4(f)(6).

<sup>13</sup> *Id.*

<sup>14</sup> In reviewing this proposal, the Commission has considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549-0609. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR-PCX-99-34 and should be submitted by November 10, 1999.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>15</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

## Exhibit A

Text of the Proposed Rule Change:<sup>16</sup>

### PCX Options: Trade-Related Charges

#### Transactions

Customer \$0.12 per contract side  
Market Maker [\$0.15 per contract side]  
*\$0.185 per contract side*

#### Firm

\$0.085 per contract side where the premium is less than \$1 per contract  
\$0.115 per contract side where the premium is \$1 or more per contract

\* \* \* \* \*  
[Book Execution Fee \$0.20 per contract side

Charge for accommodation/liquidation transactions is \$0.10 per contract.

Charge applies to book executions only and is in addition to the manual transaction charges listed above; market and marketable limit orders transacted through POETS do not receive this charge.]

\* \* \* \* \*  
[Book Staff Entry \$0.50 per entry (paid upon partial or full execution)

Charge applies to orders manually entered onto book; orders booked electronically via POETS do not receive this charge.]

\* \* \* \* \*

### [LMM BOOK PROGRAM STAFFING CHARGE

LMM monthly book contracts	Charge per book contract	Maximum charge per rate tier
First 15,000 .....	\$0.05	\$750
Next 15,000 .....	0.10	1,500
Next 25,000 .....	0.15	3,750
All contracts above 55,000	0.10	(**)

<sup>15</sup> 17 CFR 200.30-3(a)(12).

<sup>16</sup> New text is in italics. Deleted text is in brackets.

<sup>7</sup> *Supra* notes 4 and 6.

<sup>8</sup> *Id.*

<sup>9</sup> 15 U.S.C. 78f(b).

<sup>10</sup> 15 U.S.C. 78f(b)(4).

[LMM BOOK PROGRAM STAFFING  
CHARGE—Continued]

LMM monthly book contracts	Charge per book con- tract	Maximum charge per rate tier
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Book staffing charge is applied to the monthly total of all book contracts in all open issues collectively traded by an LMM under the program.]

\* Pacific Options Exchange Trading system  
\*\* No maximum.

[FR Doc. 99-27366 Filed 10-19-99; 8:45 am]

BILLING CODE 8010-01-M

## SOCIAL SECURITY ADMINISTRATION

### Senior Executive Service Performance Review Board

**AGENCY:** Social Security Administration.

**ACTION:** Notice of Senior Executive Service Performance Review Board Membership.

Title 5, U.S. Code, Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95-454, requires that the appointment of Performance Review Board members be published in the **Federal Register**.

The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Social Security Administration:

Andria Childs  
Eli N. Donkar  
Glennalee K. Donnelly  
Keith J. Fontenot  
Philip A. Gambino  
Diane B. Garro  
Richard J. Gonzalez  
Charlotte A. Hardnett  
W. Burnell Hurt  
Carmen M. Keller  
Carolyn J. Shearin-Jones  
Miguel A. Torrado  
Judy Ziolkowski

Dated: September 23, 1999.

**Paul D. Barnes,**

*Deputy Commissioner for Human Resources.*

[FR Doc. 99-27407 Filed 10-19-99; 8:45 am]

BILLING CODE 4190-29-P

## DEPARTMENT OF STATE

[Amendment of Delegation of Authority 221]

### Delegation of Authority 221-1; Director of Foreign Service and Director of Personnel

By virtue of the authority vested in me by the Secretary of State in

Delegation of Authority 148-1, dated September 9, 1981, and Delegation of Authority 198, dated September 16, 1992, Delegation of Authority 221, dated April 3, 1998, is hereby amended to read as follows:

### Delegation 221-1

#### Section 1. Functions Delegated

By virtue of the authority vested in me by the Secretary of State in Delegation of Authority 148-1, dated September 9, 1981, and Delegation of Authority 198, dated September 16, 1992, I hereby delegate to the Director General of the Foreign Service and Director of Personnel the authority vested in me:

(a) To prescribe regulations arising under the Foreign Service Act of 1980, the Civil Service Reform Act, and any other laws administered by or relating to the Bureau of Personnel and the Office of Medical Services;

(b) To exercise the functions of the Secretary under:

(1) Section 413 of the Foreign Service Act of 1980, as amended (relating to payment of a death gratuity to surviving dependents of any Foreign Service employee who dies as a result of injuries sustained in the performance of duty abroad);

(2) Section 605(b) of the Foreign Service Act of 1980, as amended (relating to removing names from rank order lists of delaying promotions);

(3) Section 607(b) of the Foreign Service Act of 1980, as amended (relating to limited career extensions);

(4) Section 609(b)(1) of the Foreign Service Act of 1980, as amended (relating to accelerating or combining installments);

(5) Section 808 of the Foreign Service Act of 1980, as amended (relating to disability retirement and related determinations);

(6) Section 901(6) of the Foreign Service Act of 1980, as amended (relating to rest and recuperation travel, including extraordinary rest and recuperation travel);

(7) Section 901(8) of the Foreign Service Act of 1980, as amended (relating to designation of posts as imminent danger areas from which family visitation travel is permitted);

(8) 5 U.S.C. 5753 and 5754 (relating to recruitment and relocation bonuses and retention allowances).

#### Section 2. Delegations Revoked

Delegations of Authority No. 224, dated September 2, 1998, and Delegation of Authority No. 132, dated July 8, 1975, 40 **Federal Register** 28646, are hereby revoked.

### Section 3. General Provisions

(a) As used in this delegation of authority, the word "function" includes any duty, obligation, power, authority, responsibility, right, privilege, discretion, or activity.

(b) The parenthetical descriptions used in this delegation of authority are not meant as words of limitation.

(c) This authority may only be re-delegated to a Deputy Assistant Secretary of State for Personnel to the extent consistent with the law.

(d) Notwithstanding any provisions of this delegation of authority, the Secretary, the Deputy Secretary, and the Under Secretary of State for Management may at any time exercise the functions herein delegated.

(e) The exercise by the Director General, or any person acting on behalf of the Director General, of the functions prescribed herein, prior to the effective date of this Delegation of Authority is hereby confirmed and ratified.

(f) An act, executive order, regulation or procedure subject to, or affected by, this delegation shall be deemed to be such act, executive order, regulation or procedure as amended from time to time.

(g) This Delegation of Authority supersedes any prior delegation on this subject to the extent such delegation may be inconsistent herewith.

Delegation of Authority 221-1 is to be published in the **Federal Register**.

Dated: October 1, 1999.

**Bonnie R. Cohen,**

*Under Secretary of State for Management.*

[FR Doc. 99-27409 Filed 10-19-99; 8:45 am]

BILLING CODE 4710-15-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-99-6350]

### Notice of Receipt of Petition for Decision That Nonconforming 1978-1980 Toyota Land Cruiser Multi-Purpose Passenger Vehicles Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 1978-1980 Toyota Land Cruiser multi-purpose passenger vehicles (MPVs) are eligible for importation.

**SUMMARY:** This notice announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1978-1980 Toyota

Land Cruiser MPVs that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into, and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

**DATE:** The closing date for comments on the petition is November 19, 1999.

**ADDRESS:** Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

**FOR FURTHER INFORMATION CONTACT:** George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

**SUPPLEMENTARY INFORMATION:**

**Background**

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports, Inc. of Lansdale, Pennsylvania ("Champagne") (Registered Importer 90-009) has petitioned NHTSA to decide whether 1978-1980 Toyota Land Cruisers that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are

eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 1978-1980 Toyota Land Cruisers that were manufactured for importation into, and sale in the United States and certified by their manufacturer, Toyota Motor Corporation, as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared the non-U.S. certified 1978-1980 Toyota Land Cruisers to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that the non-U.S. certified 1978-1980 Toyota Land Cruisers, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that the non-U.S. certified 1978-1980 Toyota Land Cruisers are identical to their U.S. certified counterparts with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence*, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 119 *New Pneumatic Tires for Vehicles other than Passenger Cars*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 203 *Impact Protection for the Driver from the Steering Control System*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Locking Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials*.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) Substitution of a lens marked "Brake" for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) installation of a seat belt warning lamp that displays the appropriate symbol; (c) recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) Installation of U.S.-model headlamp

assemblies that incorporate headlamps with DOT markings; (b) installation of U.S.-model front and rear sidemarker/reflector assemblies; (c) installation of U.S.-model taillamp assemblies.

Standard No. 111 *Rearview Mirror*: replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection*: installation of a warning buzzer microswitch in the steering lock assembly and a warning buzzer.

Standard No. 118 *Power Window Systems*: rewiring of the power window system on vehicles that are so equipped so that the window transport is inoperative when the ignition is switched off.

Standard No. 120 *Tire Selection and Rims for Motor Vehicles other than Passenger Cars*: installation of a tire information placard.

Standard No. 208 *Occupant Crash Protection*: (a) Installation of a U.S.-model seat belt in the driver's position, or a belt webbing-actuated microswitch inside the driver's seat belt retractor; (b) installation of an ignition switch-actuated seat belt warning lamp and buzzer. The petitioner states that the vehicles are equipped with combination lap and shoulder restraints that adjust by means of an automatic retractor and release by means of a single push button at both front designated seating positions, with combination lap and shoulder restraints that release by means of a single push button at both rear outboard designated seating positions, and with a lap belt in the rear center designated seating position.

Standard No. 301 *Fuel System Integrity*: installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

The petitioner also states that a vehicle identification number plate must be affixed to the vehicles to meet the requirements of 49 CFR part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 10 am to 5 pm]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition

will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: October 13, 1999.

**Marilynne Jacobs,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 99-27316 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-99-6347]

#### Notice of Receipt of Petition for Decision That Nonconforming 2000 Harley Davidson FX, FL, and XL Motorcycles Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 2000 Harley Davidson FX, FL, and XL motorcycles are eligible for importation.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 2000 Harley Davidson FX, FL, and XL motorcycles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) They are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) They are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is November 19, 1999.

**ADDRESSES:** Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 10 am to 5 pm.]

**FOR FURTHER INFORMATION CONTACT:** George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

#### SUPPLEMENTARY INFORMATION:

##### Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all

applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports of Lansdale, Pennsylvania ("Champagne") (Registered Importer 90-009) has petitioned NHTSA to decide whether non-U.S. certified 2000 Harley Davidson FX, FL, and XL motorcycles are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 2000 Harley Davidson FX, FL, and XL motorcycles that were manufactured for and sale in the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 2000 Harley Davidson FX, FL, and XL motorcycles to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 2000 Harley Davidson FX, FL, and XL motorcycles, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 2000 Harley Davidson FX, FL, and XL motorcycles are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 106 *Brake Hoses*,

111 *Rearview Mirrors*, 116 *Brake Fluid*, 119 *New Pneumatic Tires for Vehicles other than Passenger Cars*, and 122 *Motorcycle Brake Systems*.

Petitioner additionally contends that the vehicles are capable of being readily altered to meet the following standard, in the manner indicated:

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) installation of U.S.-model head lamp assemblies; and (b) installation of U.S.-model side reflex reflectors.

Standard No. 120 *Tire Selection and Rims for Vehicles other than Passenger Cars*: installation of a tire information label.

Standard No. 123 *Motorcycle Controls and Displays*: installation of a U.S.-model speedometer/odometer calibrated in miles per hour.

The petitioner also states that a vehicle identification number plate will be affixed to the vehicle to meet the requirements of 49 CFR 565.

Comments should refer to the docket number and be submitted to: Docket Management, Room PL-401, 400 Seventh Street, SW, Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: October 13, 1999.

**Marilynne Jacobs,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 99-27317 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-99-6348]

#### Notice of Receipt of Petition for Decision That Nonconforming 1998-1999 Mercedes-Benz S Class Passenger Cars Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 1998-1999

Mercedes-Benz S Class passenger cars are eligible for importation.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1998–1999 Mercedes-Benz S Class passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) They are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) They are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is November 19, 1999.

**ADDRESSES:** Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm.]

**FOR FURTHER INFORMATION CONTACT:** George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Under 49 U.S.C. § 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then

publishes this decision in the **Federal Register**.

J.K. Technologies, LLC, of Baltimore, Maryland (“J.K.”) (Registered Importer 90–006) has petitioned NHTSA to decide whether 1998–1999 Mercedes-Benz S Class passenger cars are eligible for importation into the United States. The vehicles which J.K. believes are substantially similar are 1998–1999 Mercedes-Benz S Class passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1998–1999 Mercedes-Benz S Class passenger cars to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

J.K. submitted information with its petition intended to demonstrate that non-U.S. certified 1998–1999 Mercedes-Benz S Class passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1998–1999 Mercedes-Benz S Class passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence*, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, 301 *Fuel System Integrity*, and 302 *Flammability of Interior Materials*.

Additionally, the petitioner states that non-U.S. certified 1998–1999 Mercedes-Benz S Class passenger cars comply with the Bumper Standard found in 49 CFR 581.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) Substitution of a lens marked “Brake” for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) Reprogramming of the electronic speedometer to read in miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) Installation of U.S.-model headlamps and front sidemarker lamps; (b) Installation of U.S.-model taillamp assemblies which incorporate rear sidemarker lights; (c) Installation of a U.S.-model high mounted stop lamp.

Standard No. 110 *Tire Selection and Rims*: installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection*: installation of a warning buzzer and a warning buzzer microswitch in the steering lock assembly.

Standard No. 118 *Power Window Systems*: installation of a relay in the power window system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection*: (a) Installation of a safety belt warning buzzer, wired to the driver's seat belt latch; (b) Replacement of the driver's and passenger's side air bags, control units, sensors, seat belts and knee bolsters with U.S.-model components on vehicles that are not already so equipped. The petitioner states that the vehicles are equipped at the front and rear outboard seating positions with combination lap and shoulder belts that are self tensioning and capable of being released by means of a single red push-button, and with a lap belt in the rear center designated seating position.

Standard No. 214 *Side Impact Protection*: installation of U.S.-model doorbars in vehicles that are not already so equipped.

The petitioner also states that a vehicle identification plate must be affixed to the vehicle near the left windshield post and a reference and certification label must be affixed in the area of the left front door post to meet the requirements of 49 CFR 565.

Additionally, the petitioner states that all vehicles will be inspected prior to importation to ensure that they have the requisite part markings to comply with the Theft Prevention Standard at 49 CFR 541 and that markings will be added to vehicles where needed.

Interested persons are invited to submit comments on the petition described above. Comments should refer

to the docket number and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm.] It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: October 14, 1999.

**Marilynne Jacobs,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 99-27318 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-99-6349]

#### Notice of Receipt of Petition for Decision That Nonconforming 1993-1996 Mercedes-Benz SL Series Passenger Cars Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 1993-1996 Mercedes-Benz SL Series passenger cars are eligible for importation.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1993-1996 Mercedes-Benz SL Series passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) They are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) They are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is November 19, 1999.

**ADDRESSES:** Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

**FOR FURTHER INFORMATION CONTACT:** George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

#### SUPPLEMENTARY INFORMATION:

##### Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

J.K. Technologies, LLC. of Baltimore, Maryland ("J.K.") (Registered Importer 90-006) has petitioned NHTSA to decide whether 1993-1996 Mercedes-Benz SL Series passenger cars are eligible for importation into the United States. The vehicles which J.K. believes are substantially similar are 1993-1996 Mercedes-Benz SL Series passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1993-1996 Mercedes-Benz SL Series passenger cars to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

J.K. submitted information with its petition intended to demonstrate that non-U.S. certified 1993-1996 Mercedes-Benz SL Series passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1993-1996 Mercedes-Benz SL Series passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence*, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, 301 *Fuel System Integrity*, and 302 *Flammability of Interior Materials*.

Additionally, the petitioner states that non-U.S. certified 1993-1996 Mercedes-Benz SL Series passenger cars comply with the Bumper Standard found in 49 CFR 581.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) Substitution of a lens marked "Brake" for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) Replacement of the speedometer with one calibrated in miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) Installation of U.S.-model headlamps and front sidemarker lamps; (b) Installation of U.S.-model taillamp assemblies which incorporate rear sidemarker lights; (c) Installation of a U.S.-model high mounted stop lamp.

Standard No. 110 *Tire Selection and Rims*: installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection*: installation of a warning buzzer and a

warning buzzer microswitch in the steering lock assembly.

Standard No. 118 *Power Window Systems*: installation of a relay in the power window system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection*: (a) Installation of a safety belt warning buzzer, wired to the driver's seat belt latch; (b) Replacement of the driver's and passenger's side air bags, control units, sensors, seat belts and knee bolsters with U.S.-model components on vehicles that are not already so equipped. The petitioner states that the vehicles are equipped at the front and rear outboard seating positions with combination lap and shoulder belts that are self tensioning and capable of being released by means of a single red push-button, and with a lap belt in the rear center designated seating position.

Standard No. 214 *Side Impact Protection*: installation of U.S.-model doorbars in vehicles that are not already so equipped.

The petitioner also states that a vehicle identification plate must be affixed to the vehicle near the left windshield post and a reference and certification label must be affixed in the area of the left front door post to meet the requirements of 49 CFR 565.

Additionally, the petitioner states that all vehicles will be inspected prior to importation to ensure that they have the requisite part markings to comply with the Theft Prevention Standard at 49 CFR 541.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: October 14, 1999.

**Marilynn Jacobs,**

*Director, Office of Vehicle Safety Compliance.*

[FR Doc. 99-27319 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-99-6351]

#### Notice of Receipt of Petition for Decision That Nonconforming 1994-1999 Mercedes-Benz E320 Station Wagons Are Eligible for Importation

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice of receipt of petition for decision that nonconforming 1994-1999 Mercedes-Benz E320 station wagons are eligible for importation.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1994-1999 Mercedes-Benz E320 station wagons that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is November 19, 1999.

**ADDRESSES:** Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

**FOR FURTHER INFORMATION CONTACT:** George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

#### SUPPLEMENTARY INFORMATION:

##### Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States,

certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

J.K. Motors of Baltimore, Maryland ("J.K.") (Registered Importer 90-006) has petitioned NHTSA to decide whether 1994-1999 Mercedes-Benz E320 station wagons are eligible for importation into the United States. The vehicles which J.K. believes are substantially similar are 1994-1999 Mercedes-Benz E320 station wagons that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1994-1999 Mercedes-Benz E320 station wagons to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

J.K. submitted information with its petition intended to demonstrate that non-U.S. certified 1994-1999 Mercedes-Benz E320 station wagons, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1994-1999 Mercedes-Benz E320 station wagons are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence* \* \* \*, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 204 *Steering*



*Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, 301 *Fuel System Integrity*, and 302 *Flammability of Interior Materials*.

Additionally, the petitioner states that non-U.S. certified 1994–1999 Mercedes-Benz E320 station wagons comply with the Bumper Standard found in 49 CFR part 581.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) Substitution of a lens marked “Brake” for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) replacement of the speedometer with one calibrated in miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) Installation of U.S.-model headlamps and front sidemarker lamps; (b) installation of U.S.-model taillamp assemblies which incorporate rear sidemarker lights; (c) installation of a U.S.-model high mounted stop lamp on vehicles that are not already so equipped.

Standard No. 110 *Tire Selection and Rims*: Installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: Replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection*: Installation of a warning buzzer and a warning buzzer microswitch in the steering lock assembly.

Standard No. 118 *Power Window Systems*: Installation of a relay in the power window system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection*: (a) Installation of a safety belt warning buzzer, wired to the driver's seat belt latch; (b) replacement of the driver's and passenger's side air bags, control units, sensors, seat belts and knee bolsters with U.S.-model components on vehicles that are not already so equipped. The petitioner states that the vehicles are equipped at the front and rear outboard seating positions with combination lap and shoulder belts that are self tensioning and capable of being released by means of a single red push-button, and with a lap belt in the rear center designated seating position.

Standard No. 214 *Side Impact Protection*: Installation of U.S.-model doorbars in vehicles that are not already so equipped.

The petitioner also states that a vehicle identification plate must be affixed to the vehicle near the left windshield post and a reference and certification label must be affixed in the area of the left front door post to meet the requirements of 49 CFR part 565.

Additionally, the petitioner states that all vehicles will be inspected prior to importation to ensure that they are equipped with anti-theft devices that comply with the Theft Prevention Standard at 49 CFR part 541.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Management, Room PL-401, 400 Seventh St., SW, Washington, DC 20590. (Docket hours are from 9 am to 5 pm). It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: October 15, 1999.

**Marilynne Jacobs,**

*Director, Office of Vehicle Safety Compliance.*  
[FR Doc. 99-27408 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### Research and Special Programs Administration

[Docket No. RSPA-98-4029; Notice 4]

#### Pipeline Safety: Damage Prevention “Path Forward”

**AGENCY:** Research and Special Programs Administration (RSPA); Office of Pipeline Safety (OPS).

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice is to announce a public meeting on RSPA's continuing efforts to prevent damage to underground facilities. RSPA is facilitating the establishment of a non-profit organization to advance underground facility damage

prevention. Participation from all stakeholder organizations in the damage prevention community will be necessary to ensure the most effective forum to share information. Interested parties include excavators, facility locators, railroads, local, state and federal government agencies, and owners and operators of underground facilities, as well as the general public.

**DATES:** The public meeting will be held on Thursday, October 28, 1999, from 9:00 am to 4:30 pm.

**ADDRESSES:** The public meeting will be held at the Omni Inner Harbor Hotel, 101 West Fayette Street, Baltimore, MD 21202. A block of rooms is being held for the “U.S. DOT Damage Prevention Meeting.”

**FOR FURTHER INFORMATION CONTACT:** Eben M. Wyman, (202) 366-0918, or by e-mail at eben.wyman@rspa.dot.gov, regarding the subject matter of this notice.

#### Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact Eben Wyman at the address or phone number listed under **FOR FURTHER INFORMATION CONTACT** as soon as possible.

**SUPPLEMENTARY INFORMATION:** On June 30, 1999, RSPA held a public meeting in Washington, DC, to present to the Secretary of Transportation a report on damage prevention best practices, as required by the Transportation Equity Act for the 21st Century (TEA-21). The “Common Ground Study” was developed by over 160 volunteers who worked for nearly a year to produce this report on best practices in damage prevention. The study identifies and evaluates existing underground damage prevention practices that are most effective in protecting the public, excavators, and the environment. These practices prevent disruptions to public services and damage to underground facilities, such as water, sewer, natural gas and hazardous liquid pipelines, as well as copper and fiber optic telecommunications cables and electric ductwork and cables. A major point of interest at the June 30th meeting was on the next steps to be taken in damage prevention, also referred to as the “path forward.”

A key lesson of Common Ground Study was that full representation and motivated commitment from all key stakeholders is essential. To effectively develop a “path forward,” we need input from the full spectrum of stakeholders to ensure that all affected

parties are provided with the opportunity to contribute and participate. Following the Common Ground Study model, RSPA believes that all stakeholder organizations should participate in this public meeting to share their ideas and express their interest in the "path forward" in damage prevention.

### Topics of Discussion

RSPA asks attendees at the meeting to identify those organizations and industry leaders whose high level commitment, leadership, and influence are essential to complete planning for establishment of the damage prevention non-profit organization. RSPA also seeks comment on the mission, goals, functions, and organizational structure of the non-profit organization. Interested stakeholders are encouraged to propose guiding principles to shape the formation of the organization to best address the many issues involved in protecting the nation's underground infrastructure from outside force damage.

RSPA strongly supports the need for an organized effort to address damage prevention challenges in the years ahead. With the support of Congress and the Department of Transportation, we are committed to provide resources to the effort. However, RSPA believes the future of damage prevention lies in the hands of the private sector. RSPA is working to assist the initial creation of a self-sustaining private sector, non-profit organization on a temporary basis only, to ensure the participation of all affected stakeholders. The U.S. Senate Appropriations Committee report on Fiscal Year 2000 appropriations directed RSPA to "support the formation and initial operation" of the organization. Once the organization is formed, the federal government's role will become much less significant.

We enjoyed our role in organizing, facilitating, and managing the Common Ground Study Team and we plan to support this effort. RSPA welcomes all interested parties to attend and participate in this public meeting to take the next steps necessary in promoting and encouraging underground facility damage prevention.

Issued in Washington, DC on October 14, 1999.

**Richard B. Felder,**

*Associate Administrator for Pipeline Safety.*  
[FR Doc. 99-27320 Filed 10-19-99; 8:45 am]

BILLING CODE 4910-60-P

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

[STB Docket No. MC-F-20956]<sup>1</sup>

#### Northwest Motor Coach L.L.C.— Control—Evergreen Stage Line, Inc. and Evergreen Bus Company, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving finance application and granting interim approval.<sup>2</sup>

**SUMMARY:** Northwest Motor Coach L.L.C. (Northwest) and L & K Acquisition Corp. (L & K), two noncarrier holding companies, and Evergreen Stage Line, Inc. (ESL) and Evergreen Bus Company, Inc. (EBC), two regulated motor passenger carriers, all of Portland, OR (collectively, applicants), have filed: (1) An application under 49 U.S.C. 14303(a) for Northwest to acquire control of ESL and EBC; and (2) a request for interim approval of the transaction under 49 U.S.C. 14303(i) pending determination of the application. Persons wishing to oppose the application must follow the rules at 49 CFR part 1182, subpart B. The Board has tentatively approved the application. If no opposing comments are timely filed, this notice will be the final Board action.

**DATES:** Comments are due by December 6, 1999. Applicants may reply by December 21, 1999. If no comments are received by December 6, 1999, this approval is effective on that date.

**ADDRESSES:** Send an original and 10 copies of any comments referring to STB Docket No. MC-F-20956 to: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423-0001. In addition, send one copy of any comments to applicants' representative: Jeremy Kahn, Kahn & Kahn, 1730 Rhode Island Ave., NW, Suite 810, Washington, DC 20036.

**FOR FURTHER INFORMATION CONTACT:** Joseph H. Dettmar, (202) 565-1600. (TDD for the hearing impaired: (202) 565-1695.)

<sup>1</sup> This proceeding embraces STB Docket No. MC-F-20956 TA.

<sup>2</sup> Interim approval will be effective on October 18, 1999.

### SUPPLEMENTARY INFORMATION:

Applicants state that ESL<sup>3</sup> and EBC<sup>4</sup> are currently controlled by L & K; Northwest is controlled by Larry S. Black and Jerry L. Kilb. L & K owns all of the stock of ESL, and ESL, in turn, owns all of the stock of EBC. Applicants state that none of the entities involved in this proceeding is affiliated with any other motor carrier, except that Jerry L. Kilb, a principal in L & K and president of ESL and EBC, is a principal of Northwest and will remain president of ESL and EBC following the proposed transaction.

Applicants state that: (1) L & K has agreed to sell Northwest all of its assets (including its stock in ESL) and all of its liabilities; (2) upon consummation of the transaction, Northwest will control two regulated passenger carriers and the previous shareholders of L & K will own approximately 7.5% of the shares of Northwest; and (3) L & K will no longer have any control of any regulated passenger carriers.

Applicants state that the proposed transaction will have no impact on the adequacy of transportation services available to the public. The proposal involves only a sale of the two carriers from one holding company to a second, and there will be no change in carrier operations. Applicants assert that Northwest's acquisition of control, with a new infusion of funds, will assure the continued viability of ESL and EBC and result in the continued availability of adequate service to the public.

According to applicants, the transaction includes a fixed payment to L & K shareholders which can readily be paid from Northwest's equity investment and third party financing without affecting carrier operations. Applicants add that no carrier employees will be adversely affected by the transaction, as the carriers will continue to perform the same operations with the same employees.

Applicants certify that: (1) ESL and EBC hold a satisfactory safety rating

<sup>3</sup> ESL holds federally-issued operating authority in Docket No. MC-29839, authorizing the transportation of passengers in charter and special operations, between points in the United States. It also holds Motor Carrier Permit No. 118436 issued by the Oregon Public Utility Commission authorizing certain intrastate operations. ESL had gross operating revenues of \$1,860,000 for the 12-month period ending June 30, 1999.

<sup>4</sup> EBC holds federally-issued operating authority in Docket No. MC-39416, authorizing the transportation of passengers, in charter and special operations, between points in the United States. It also holds a Motor Carrier Certificate in File No. 237, Class 1P, MEP 960003 issued by the Oregon Department of Transportation, authorizing certain intrastate operations. EBC had gross operating revenues of \$4,450,000 for the 12-month period ending June 30, 1999.

from the U.S. Department of Transportation; (2) ESL and EBC maintain sufficient liability insurance; (3) none of the involved carriers is domiciled in Mexico nor owned or controlled by persons of that country; and (4) approval of the transaction will not significantly affect either the quality of the human environment or the conservation of energy resources.

Under 49 U.S.C. 14303(b), the Board must approve and authorize transactions it finds consistent with the public interest, taking into account at least: (1) The effect of the transactions on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees.

On the basis of the application, we find that the proposed acquisition of control is consistent with the public interest and should be authorized. If any opposing comments are timely filed, this finding will be deemed vacated and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application.<sup>5</sup> If no opposing comments are filed by the expiration of the comment period, this decision will take effect automatically and will be the final Board action.

In their interim approval request, applicants state that, because the current owners of ESL and EBC are not prepared to make necessary long term investments in them, it is necessary that Northwest be allowed to assume their temporary control on or immediately after October 18, 1999, or the carriers could lose their market position to competitors, thereby causing severe injury to the ESL and EBC properties. Applicants have explained that the failure to grant such interim approval may result in injury to the motor carrier properties or substantially interfere with their future usefulness in providing adequate and continuous service to the public. Accordingly, the interim approval will be granted.<sup>6</sup>

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

*It is ordered:*

<sup>5</sup> Under 49 CFR 1182.6(c), a procedural schedule will not be issued if we are able to dispose of opposition to the application on the basis of comments and the reply.

<sup>6</sup> The Board will entertain petitions to reconsider a grant of interim approval. Such petitions may be filed only by a person who has filed a comment in opposition to the application. See 49 U.S.C. 1182.7(e) for further details.

1. Northwest's control of ESL and EBC is approved and authorized, subject to the filing of opposing comments.

2. Northwest is granted interim approval to operate the properties of ESL and EBC for a period of not more than 180 days pending determination of the application.

3. If timely opposing comments are filed, the findings made in this decision will be deemed vacated.

4. This decision will be effective on December 6, 1999, unless timely opposing comments are filed.

5. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Office of Motor Carriers-HIA 30, 400 Virginia Avenue, SW, Suite 600, Washington, DC 20024; (2) the U.S. Department of Transportation, Office of the General Counsel, 400 7th Street, SW, Washington, DC 20590; and (3) the U.S. Department of Justice, Antitrust Division, 10th Street and Pennsylvania Avenue, NW, Washington, DC 20530.

By the Board, Chairman Morgan, Vice Chairman Clyburn, and Commissioner Burkes.

Decided: October 14, 1999.

**Vernon A. Williams,**  
Secretary.

[FR Doc. 99-27412 Filed 10-19-99; 8:45 am]

BILLING CODE 4915-00-P

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

[STB Finance Docket No. 33802]

#### Delta Southern Railroad, Inc.— Acquisition and Operation Exemption—Delta Southern Railroad Company

Delta Southern Railroad, Inc. (Delta), a noncarrier, newly created to become a Class III railroad, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire (by purchase or lease) and operate approximately 132.78 miles of rail line from Delta Southern Railroad Company (DSRR). The lines or rights intended to be acquired are as follows: (1) From milepost 408.9 in or near McGehee, AR, to milepost 489.44 in or near Tallulah, LA; (2) a rail spur from milepost 445.53 (where it connects with the Warren Line described in (3)(a)) for 3 miles;<sup>1</sup> and (3) DSRR's leasehold interest in a rail line owned by Union Pacific Railroad Company (UP) and currently operated by DSRR (a) from milepost 422.32 at Dermott, AR, to

milepost 461.74 at Warren, AR (The Warren Line), and (b) from milepost 566 at Monroe, LA, to milepost 556.18 at Sterlington, LA (The Sterlington Line). In addition, Delta will acquire approximately 11.76 miles of operating rights over other rail lines: (1) DSRR's operating rights over certain other rail assets located at milepost 491 in Tallulah, LA, and owned by the Madison Parish Port Commission (The Madison Line); (2) certain overhead trackage rights over UP's line (a) between milepost 415.26 at Dermott, AR, and milepost 409.7 at McGehee, AR, and (b) and yard facilities from milepost 566 and milepost 500.3 to milepost 504 at Monroe, LA; and (3) certain operating rights at milepost 472.8 at Lake Providence, LA, owned by the Lake Providence Port Commission.<sup>2</sup>

On August 4, 1999, William and Linda Wainwright, sole owners of Delta signed a letter of intent with Lawrence Beal for the parties to negotiate and execute a purchase and sale agreement for the acquisition and operation of DSRR.<sup>3</sup> The verified notice states that William Wainwright has managed DSRR for the past 10 years since DSRR was established as a short line railroad in 1989. The parties had not yet signed an agreement as of the October 1, 1999 filing of the verified notice of exemption.

The transaction is scheduled to be consummated on or shortly after October 18, 1999.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33802, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on John D. Heffner, Esq., Rea, Cross, & Auchincloss, 1707 L Street, NW, Suite 570, Washington, DC 20036.

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

Decided: October 12, 1999.

<sup>2</sup> Delta states that its projected revenues will not exceed those that would qualify it as a Class III rail carrier and that its revenues are not projected to exceed \$5 million.

<sup>3</sup> Lawrence Beal owns 100% of DSRR.

<sup>1</sup> Delta indicated in its notice that it takes no position on whether this line is a spur for the purpose of the spur exemption under 49 U.S.C. 10906.

By the Board, David M. Konschnik,  
Director, Office of Proceedings.

**Vernon A. Williams,**  
Secretary.

[FR Doc. 99-27131 Filed 10-19-99; 8:45 am]

BILLING CODE 4915-00-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### Proposed Collection; Comment Request; Lien Notice (Customs Form 3485)

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. Customs Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, D.C. 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, D.C. 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide

information. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting information collection:

*Title:* Lien Notice.

*OMB Number:* 1515-0046.

*Form Number:* Customs Form 3485.

*Abstract:* The Lien Notice, Customs Form 3485, enable the carriers, cartmen, and similar businesses to notify Customs that a lien exists against an individual/business for non-payment of freight charges, etc., so that Customs will not permit delivery of the merchandise from public stores or a bonded warehouse until the lien is satisfied or discharged.

*Current Actions:* There are no changes to the information collection. This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Individuals, businesses.

*Estimated Number of Respondents:* 2,000.

*Estimated Time Per Respondent:* 5 minutes.

*Estimated Total Annual Burden Hours:* 8,497.

*Estimated Total Annualized Cost on the Public:* N/A.

Dated: October 14, 1999.

**J. Edgar Nichols,**

Agency Clearance Officer, Information Services Group.

[FR Doc. 99-27345 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### Proposed Collection; Comment Request; Importers of Merchandise Subject to Actual Use Provisions

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. Customs Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, D.C. 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, D.C. 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

*Title:* Importers of Merchandise Subject to Actual Use Provisions.

*OMB Number:* 1515-0091.

*Form Number:* None.

*Abstract:* The Importers of Merchandise Subject to Actual Use Provision is part of the regulation which provides that certain items may be admitted duty-free such as farming implements, seed, potatoes etc., providing the importer can prove these items were actually used as contemplated by law. The importer must maintain detailed records and furnish a statement of use.

*Current Actions:* There are no changes to the information collection. This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Individuals, Businesses.

*Estimated Number of Respondents:* 12,000.

*Estimated Time Per Respondent:* 60 minutes.

*Estimated Total Annual Burden Hours:* 12,000.

*Estimated Total Annualized Cost on the Public:* N/A.

Dated: October 14, 1999.

**J. Edgar Nichols,**

*Agency Clearance Officer, Information Services Group.*

[FR Doc. 99-27346 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### **Proposed Collection; Comment Request; Proof of the Use for Rates of Duty Dependent on Actual Use**

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. Customs Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, DC 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d)

ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

*Title:* Proof of the Use for Rates of Duty Dependent on Actual Use.

*OMB Number:* 1515-0109.

*Form Number:* None.

*Abstract:* The Proof of the Use for Rates of Duty Dependent on Actual Use declaration is needed to ensure Customs control over merchandise which is duty free. The declaration shows proof of use and must be submitted within 3 years of the date of entry or withdrawal for consumption.

*Current Actions:* There are no changes to the information collection. This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Individuals, Businesses.

*Estimated Number of Respondents:* 10,500.

*Estimated Time Per Respondent:* 20 minutes.

*Estimated Total Annual Burden*

*Hours:* 3,500.

*Estimated Total Annualized Cost on the Public:* N/A.

Dated: October 14, 1999.

**J. Edgar Nichols,**

*Agency Clearance Officer, Information Services Group.*

[FR Doc. 99-27347 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### **Proposed Collection; Comment Request; Required Records for Smelting and Refining Warehouses**

**AGENCY:** U.S. Customs, Department of the Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to

comment on an information collection requirement concerning the Required Records for Smelting and Refining Warehouses. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, DC 20229.

#### **FOR FURTHER INFORMATION CONTACT:**

Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, DC 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting information collection:

*Title:* Required Records for Smelting and Refining Warehouses.

*OMB Number:* 1515-0135.

*Form Number:* N/A.

*Abstract:* Each manufacturer engaged in smelting or refining must file an annual statement showing any material change in the character of the metal-bearing materials used or changes in the method of smelting or refining. Also, the records must show the receipt and disposition of each shipment.

*Current Actions:* There are no changes to the information collection.

*Type of Review:* Extension (without change).

*Affected Public:* Business or other for-profit institutions.

*Estimated Number of Respondents:* 15.

*Estimated Time Per Respondent:* 85 hours.

*Estimated Total Annual Burden Hours:* 1,325.

*Estimated Total Annualized Cost on the Public:* \$15,900.

Dated: October 14, 1999.

**J. Edgar Nichols,**

*Agency Clearance Officer, Printing and Records Services Group.*

[FR Doc. 99-27348 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### **Proposed Collection; Comment Request; Declaration of Person Who Performed Repairs**

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. Customs Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, DC 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including

whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

*Title:* Declaration of Person Who Performed Repairs.

*OMB Number:* 1515-0137.

*Form Number:* None.

*Abstract:* The Declaration of Person Who Performed Repairs is used by Customs to ensure duty-free status for entries covering articles repaired aboard. It must be filed by importers claiming duty-free status.

*Current Actions:* There are no changes to the information collection. This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses or other for-profit.

*Estimated Number of Respondents:* 10,236.

*Estimated Time Per Respondent:* 30 minutes.

*Estimated Total Annual Burden Hours:* 10,236.

*Estimated Total Annualized Cost on the Public:* N/A.

Dated: October 14, 1999.

**J. Edgar Nichols,**

*Agency Clearance Officer, Information Services Group.*

[FR Doc. 99-27349 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Customs Service

#### **Proposed Collection; Comment Request User Fees (Customs Form 339)**

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent

burden, Customs invites the general public and other Federal agencies to comment on an information collection requirement concerning the U.S. Customs Declaration. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Public Law 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 20, 1999, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs Service, Information Services Group, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue, NW, Room 3.2C, Washington, D.C. 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to U.S. Customs Service, Attn.: J. Edgar Nichols, 1300 Pennsylvania Avenue NW, Room 3.2C, Washington, D.C. 20229, Tel. (202) 927-1426.

**SUPPLEMENTARY INFORMATION:** Customs invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the Customs request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document Customs is soliciting comments concerning the following information collection:

*Title:* User Fees.

*OMB Number:* 1515-0154.

*Form Number:* Customs Form 339.

*Abstract:* The User Fees, Customs Form 339, information is necessary for Customs to effectively collect fees from private and commercial vessels, private aircraft, operators of commercial trucks, and passenger and freight railroad cars entering the United States and

recipients of certain dutiable mail entries for certain official services.

**Current Actions:** There are no changes to the information collection. This submission is being submitted to extend the expiration date.

**Type of Review:** Extension (without change).

**Affected Public:** Businesses or other for-profit.

**Estimated Number of Respondents:** 200,000.

**Estimated Time Per Respondent:** 15 minutes.

**Estimated Total Annual Burden Hours:** 50,000.

**Estimated Total Annualized Cost on the Public:** N/A.

Dated: October 14, 1999.

**J. Edgar Nichols,**

Agency Clearance Officer, Information Services Group.

[FR Doc. 99-27350 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF THE TREASURY

### Financial Crimes Enforcement Network

#### Customs Service

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Report of International Transportation of Currency or Monetary Instruments

**AGENCY:** Financial Crimes Enforcement Network (FinCEN) and United States Customs Service (Customs).

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, FinCEN and Customs invite the general public and other Federal agencies to comment on an information collection requirement concerning the Report of International Transportation of Currency or Monetary Instruments. This request for comment 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 should be received on or before December 20, 1999 to be assured of consideration.

**ADDRESSES:** Direct all written comments to: FinCEN: Office of Chief Counsel, Financial Crimes Enforcement Network, Department of the Treasury, Suite 200, 2070 Chain Bridge Road, Vienna, VA 22182-2536. **Attention:** PRA Comments—Report of International Transportation of Currency or Monetary Instruments. Comments also may be

submitted by electronic mail to the following Internet address:

“regcomments@fincen.treas.gov” with the caption in the body of the text, “**Attention:** PRA Comments—Report of International Transportation of Currency or Monetary Instruments.”

**Customs:** U.S. Customs Service, Attn.: Joseph R. Catanzarite, Financial Investigations, 1300 Pennsylvania Ave., NW, Room 7.2C, Washington, DC 20229.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or for a copy of the form should be directed to: FinCEN: Christine Schuetz, Attorney-Advisor, FinCEN, at (703) 905-3644, or Anna Fotias, Chief, Regulatory Outreach Programs, FinCEN, at (703) 905-3695.

**Customs:** U.S. Customs Service, Attn.: Joseph R. Catanzarite, 1300 Pennsylvania Ave., NW, Room 7.2C, Washington, DC 20229. Tel. (202) 927-1520.

#### SUPPLEMENTARY INFORMATION:

**Title:** Report of International Transportation of Currency or Monetary Instruments.

**OMB Number:** 1515-0079.

**Form Number:** Customs Form 4790.

**Abstract:** The Bank Secrecy Act, Titles I and II of Pub. L. 91-508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5330, authorizes the Secretary of the Treasury, *inter alia*, to issue regulations requiring records and reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters. Regulations implementing Title II of the Bank Secrecy Act (codified at 31 U.S.C. 5311-5330) appear at 31 CFR part 103. The authority of the Secretary to administer Title II of the Bank Secrecy Act has been delegated to the Director of FinCEN.

The Bank Secrecy Act specifically states that “a person or an agent or bailee of the person shall file a report \* \* \* when the person, agent, or bailee knowingly—(1) transports, is about to transport, or has transported, monetary instruments of more than \$10,000 at one time—(A) from a place in the United States to or through a place outside the United States; or (B) to a place in the United States from or through a place outside the United States; or (2) receives monetary instruments of more than \$10,000 at one time transported into the United States from or through a place outside the United States.” 31 U.S.C. 5316(a). The requirement of 31 U.S.C. 5316(a) has been implemented through regulations promulgated at 31 CFR 103.23 and through the instructions to the Report of International Transportation of Currency or Monetary

Instruments (CMIR), U.S. Customs Service Form 4790.

Information collected on the CMIR is made available, in accordance with strict safeguards, to appropriate criminal law enforcement and regulatory personnel in the official performance of their duties. The information collected is of use in investigations involving international and domestic money laundering, tax evasion, fraud, and other financial crimes.

**Current Actions:** The CMIR is being revised to clarify the instructions to the form. The form is also being streamlined by combining Parts I and II of the form now in use into one part; as a result, the items on the form are being renumbered. Finally, two questions on the form are being revised slightly to make them more useful. Question 15 of Part II (question 27c of the form now in use) is revised to add after “Type of Business Activity, Occupations, or Profession” a box to check when the business is a bank. Under Part III, Currency and Monetary Instrument Information, the entry for other instruments is revised to read “Specify type, issuing entity and date, and serial or other identifying number.”

**Type of Review:** Revision of currently approved collection.

**Affected Public:** Individuals, business or other for-profit institutions, not-for-profit institutions.

**Estimated Number of Respondents:** 180,000.

**Estimated Time Per Respondent:** 11 minutes.

**Estimated Total Annual Burden Hours:** 33,000 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. Generally, information collected pursuant to the Bank Secrecy Act is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

#### 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 14, 1999.

**James F. Sloan,**

*Director, Financial Crimes Enforcement Network, Department of the Treasury.*

Dated: October 12, 1999.

**J. Edgar Nichols,**

*Team Leader, Information Services Group, United States Customs Service.*

[FR Doc. 99-27403 Filed 10-19-99; 8:45 am]

BILLING CODE 4820-03-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

[LR-274-81]

#### 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, LR-274-81 (TD 8067), Accounting for Long-Term Contracts (§ 1.451-3).

**DATES:** Written comments should be received on or before December 20, 1999 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulation should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

#### SUPPLEMENTARY INFORMATION:

*Title:* Accounting for Long-Term Contracts.

*OMB Number:* 1545-0736.

*Regulation Project Number:* LR-274-81.

**Abstract:** The recordkeeping requirements in this regulation are necessary to determine whether taxpayers are properly allocating indirect contract costs to extended period long-term contracts. The information will be used to verify the taxpayer's allocations of indirect costs and to ensure compliance with the cost-accounting principles of § 1.451-3 of the regulations.

**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.

**Estimated Number of Respondents:** 1,000.

**Estimated Time Per Respondent:** 10 hours, 1 minute.

**Estimated Total Annual Burden Hours:** 10,010.

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 14, 1999.

**Garrick R. Shear,**

*IRS Reports Clearance Officer.*

[FR Doc. 99-27414 Filed 10-19-99; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

[FI-81-86]

#### 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, FI-81-86(TD 8513), Bad Debt Reserves of Banks (§ 1.585-8).

**DATES:** Written comments should be received on or before December 20, 1999 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulation should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

#### SUPPLEMENTARY INFORMATION:

*Title:* Bad Debt Reserves of Banks.

*OMB Number:* 1545-1290.

*Regulation Project Number:* FI-81-86.

**Abstract:** Section 585(c) of the Internal Revenue Code requires large banks to change from the reserve method of accounting to the specific charge off method of accounting for bad debts. Section 1.585-8 of the regulation contains reporting requirements in cases in which large banks elect (1) To include in income an amount greater than that prescribed by the Code; (2) To use the elective cut-off method of accounting; or (3) To revoke any elections previously made.

**Current Actions:** There is no change to these existing regulations.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents:* 2,500.

*Estimated Time Per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 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 13, 1999.

**Garrick R. Shear,**

*IRS Reports Clearance Officer.*

[FR Doc. 99-27415 Filed 10-19-99; 8:45 am]

BILLING CODE 4830-01-U

#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

#### Proposed Collection; Comment Request for Revenue Procedure 99-39

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 99-39, Form 941 e-file Program.

**DATES:** Written comments should be received on or before December 20, 1999 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the revenue procedure should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

#### SUPPLEMENTARY INFORMATION:

*Title:* Form 941 e-file Program.

*OMB Number:* 1545-1557.

*Revenue Procedure Number:* Revenue Procedure 99-39.

*Abstract:* Revenue Procedure 99-39 provides the requirements of the Form 941 e-file Program, which combines the Form 941 Electronic Filing (ELF) Program with an on-line filing program that allows a taxpayer to electronically file a Form 941, Employer's Quarterly Federal Tax Return, using a personal computer, modem, and commercial tax preparation software.

*Current Actions:* There are no changes being made to the revenue procedure at this time.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations, not-for-profit institutions, and Federal, state, local or tribal governments.

*Estimated Number of Respondents/Recordkeepers:* 390,200.

*Estimated Average Time Per Respondent/Recordkeeper:* 37 minutes.

*Estimated Total Annual Reporting/Recordkeeping Burden Hours:* 238,863.

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 13, 1999.

**Garrick R. Shear,**

*IRS Reports Clearance Officer.*

[FR Doc. 99-27416 Filed 10-19-99; 8:45 am]

BILLING CODE 4830-01-U

#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

#### Defined Benefit Pension Plans; Solicitation for Comments

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Solicitation for comments.

**SUMMARY:** The IRS and the Department of the Treasury are seeking public comments regarding potential issues arising under their jurisdiction with respect to retirement plans known as cash balance pension plans ("cash balance plans"), particularly with respect to conversions of other types of defined benefit pension plans into cash balance plans. The purpose of these comments is to provide the IRS and Treasury with information that may be taken into account in their analysis of these issues.

**DATES:** Comments are requested on or before January 19, 2000.

**ADDRESSES:** Send written comments to: Internal Revenue Service, Attn: CC:DOM:CORP:R (Cash Balance Plans and Conversions), Room 5226, P.O. Box 7604, Ben Franklin Station, Washington,

DC 20044. Written comments may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: Internal Revenue Service, Courier's Desk, Attn: CC:DOM:CORP:R (Cash Balance Plans and Conversions), 1111 Constitution Avenue, NW, Washington, DC 20224. Alternatively, written comments may be submitted electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting them directly to the IRS Internet site at: [http://www.irs.gov/tax\\_regs/regslst.html](http://www.irs.gov/tax_regs/regslst.html).

**FOR FURTHER INFORMATION CONTACT:** Mr. Kenneth M. Griffin, (202) 622-4604 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

A cash balance plan is a defined benefit pension plan that typically defines an employee's retirement benefit by reference to the amount of a hypothetical account balance. In a typical cash balance plan, this account is credited with hypothetical allocations and interest that are determined under a formula set forth in the plan. The crediting of hypothetical allocations and hypothetical interest has been described as resembling the allocation of actual contributions and actual earnings to an employee's account under a defined

contribution plan, such as a profit-sharing plan.

In recent years, existing defined benefit plans covering a significant number of employees have been changed into cash balance plans. This change, made by amending the existing plan, is commonly referred to as a conversion. In a conversion, the new cash balance benefit formula generally applies to new employees and may also apply to employees who had already earned benefits under the plan before the conversion. The law protects benefits earned before the conversion by prohibiting a plan amendment that reduces those benefits.

In some conversions, however, employees who had already earned benefits may not earn additional retirement benefits for varying periods of time after the conversion. This effect, often referred to as a "wear-away" or "benefit plateau," continues until an employee's benefit under the ongoing cash balance formula "catches up" with the employee's protected benefit.

**Comments**

The IRS and Treasury invite public comments regarding potential issues under their jurisdiction with respect to cash balance plans, conversions of traditional defined benefit plans to cash

balance plans, and associated wear-away or benefit plateau effects. All comments submitted will be made available for public inspection and copying, although the comments will not be individually acknowledged. Therefore, commentators should refrain from including personal tax information or other information that they believe should not be publicly disclosed.

The IRS and Treasury would like to receive comments from the full range of parties with interests in cash balance and similar plans, including employees, employers, and their representatives. The review of the legal issues relating to cash balance and similar plans is being coordinated with the agencies that have concurrent or overlapping jurisdiction over other Federal laws (such as the Age Discrimination in Employment Act (ADEA) and Employee Retirement Income Security Act (ERISA)). Accordingly, copies of comments received that relate to those laws will be provided to the appropriate agencies.

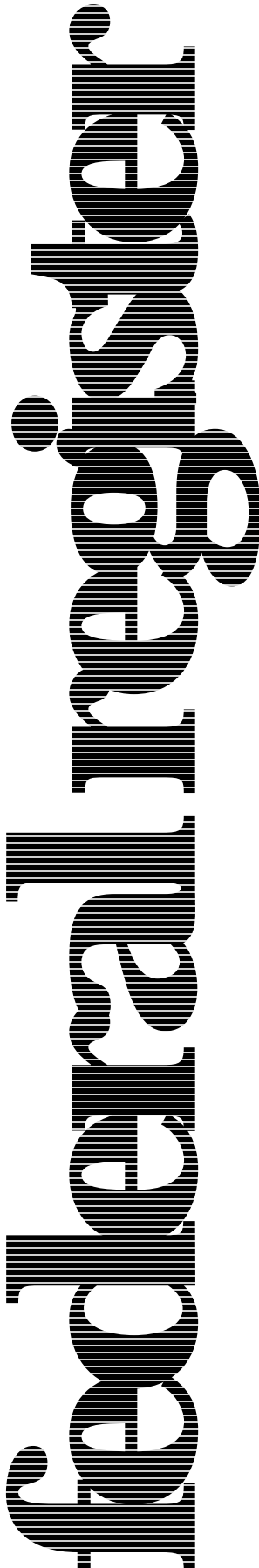
Dated: October 13, 1999.

**Nancy J. Marks,**

*Acting Associate Chief Counsel, Employee Benefits and Exempt Organizations, Internal Revenue Service.*

[FR Doc. 99-27148 Filed 10-19-99; 8:45 am]

BILLING CODE 4830-01-U



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Wednesday  
October 20, 1999

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## Part II

# Department of the Interior

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Fish and Wildlife Service

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### 50 CFR Part 17

Endangered and Threatened Wildlife and  
Plants; Listing *Helianthus paradoxus*  
(Pecos Sunflower), Devils River Minnow  
and *Astragalus desereticus* (Deseret milk-  
vetch) as Threatened; Final Rules

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

RIN 1018-AE88

**Endangered and Threatened Wildlife and Plants; Determination of Threatened Status for the Plant *Helianthus paradoxus* (Pecos Sunflower)**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the Fish and Wildlife Service (Service) determine *Helianthus paradoxus* (Pecos or puzzle sunflower) to be a threatened species under the authority of the Endangered Species Act of 1973, as amended (Act). This species is dependent on desert wetlands for its survival. It is known from 22 sites in Cibola, Valencia, Guadalupe, and Chaves counties, New Mexico, and from 3 sites in Pecos and Reeves counties, Texas. Threats to this species include drying of wetlands from groundwater depletion, alteration of wetlands (e.g. wetland fills, draining, impoundment construction), competition from non-native plant species, excessive livestock grazing, mowing, and highway maintenance. This rule implements the Federal protection and recovery programs of the Act for this plant.

**DATES:** This rule is effective November 19, 1999.

**ADDRESSES:** The complete file for this rule is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna Road, NE, Albuquerque, New Mexico 87113.

**FOR FURTHER INFORMATION CONTACT:** Charlie McDonald, Botanist, at the above address (telephone 505-346-2525 ext. 112; facsimile 505-346-2542).

**SUPPLEMENTARY INFORMATION:**

**Background**

Dr. S.W. Woodhouse, physician and naturalist, was the first person to collect Pecos sunflower on August 26, 1851, while on the Sitgreaves expedition to explore the Zuni River and the Lower Colorado. The location was given as "Nay Camp, Rio Laguna" (Sitgreaves 1853). The collection site is probably located somewhere near the Rio Laguna (now called the Rio San Jose) between Laguna Pueblo and Bluewater in Cibola County, New Mexico. Dr. John Torrey, a botanical expert at the New York Botanical Garden, identified this

specimen as *Helianthus petiolaris* (prairie sunflower) (Sitgreaves 1853). It was not until 1958 that Dr. Charles Heiser named *Helianthus paradoxus* as a new species citing two known specimens, the type specimen collected September 11, 1947, by H.R. Reed west of Fort Stockton in Pecos County, Texas, and the Woodhouse specimen collected in New Mexico (Heiser 1958).

Heiser's (1965) hybridization studies helped resolve doubts about the validity of Pecos sunflower as a true species. Prior to Heiser's studies there was some speculation the plant was a hybrid between *Helianthus annuus* (common sunflower) and the prairie sunflower. Heiser's studies demonstrated that Pecos sunflower is a fertile plant that breeds true. Heiser was able to produce hybrids between Pecos sunflower and both common sunflower and prairie sunflower, but these hybrids were of low fertility. These results support the validity of Pecos sunflower as a true species. In 1990, Rieseberg *et al.* published the results of molecular tests on the hypothesized hybrid origin of Pecos sunflower, using electrophoresis to test enzymes and restriction-fragment analysis to test ribosomal and chloroplast DNA. This work identified Pecos sunflower as a true species of ancient hybrid origin with the most likely hybrid parents being common sunflower and prairie sunflower.

Pecos sunflower is an annual member of the sunflower family (Asteraceae). It grows 1.3–2.0 meters (m) (4.25–6.5 feet (ft)) tall and is branched at the top. The leaves are opposite on the lower part of the stem and alternate at the top. The leaves are lance-shaped with three prominent veins, and up to 17.5 centimeters (cm) (6.9 inches (in)) long by 8.5 cm (3.3 in) wide. The stem and leaf surfaces have a few short stiff hairs. The flower heads are 5.0–7.0 cm (2.0–2.8 in) in diameter with bright yellow rays. Flowering is from September to November. Pecos sunflower looks much like the common sunflower seen along roadsides throughout the west, but differs from common sunflower in having narrower leaves, fewer hairs on the stems and leaves, slightly smaller flower heads, and flowers later.

Pecos sunflower grows in permanently saturated soils. Areas with these conditions are most commonly desert wetlands (ciénegas) associated with springs, but may also include stream and lake margins. When plants grow around lakes, the lakes are usually impounded natural ciénega habitats. Plants commonly associated with Pecos sunflower include *Limonium limbatum* (Transpecos sealavender), *Samolus cuneatus* (limewater brookweed),

*Flaveria chloraefolia*, *Scirpus olneyi* (Olney bulrush), *Phragmites australis* (common reed), *Distichlis* sp. (saltgrass), *Sporobolus airoides* (alkali sacaton), *Muhlenbergia asperifolia* (alkali muhly), *Juncus mexicanus* (Mexican rush), *Suaeda calceoliformis* (Pursh seepweed), and *Tamarix* spp. (saltcedar) (Poole 1992, Sivinski 1995). All of these species are good indicators of saline soils. Van Auken and Bush (1995) did studies that show Pecos sunflower grows in saline soils, but seeds germinate and establish best when high water tables reduce salinities near the soil's surface.

Until 1990, Pecos sunflower was known from only three extant sites. Two sites were in Pecos County, Texas, and one site was in Chaves County, New Mexico (Seiler *et al.* 1981). Searches of suitable habitats in Pecos, Reeves, and Culbertson counties, Texas, during 1991 failed to locate any new Texas sites (Poole 1992). However, searches in New Mexico from 1991 through 1994 located a significant number of new sites (Sivinski 1995). In Texas one new site was reported in 1998 (Kargas 1998).

Pecos sunflower is presently known from 25 sites that occur in 5 general areas. These areas are Pecos and Reeves counties, Texas, in the vicinity of Fort Stockton and Balmorhea; Chaves County, New Mexico, from Dexter to just north of Roswell; Guadalupe County, New Mexico, in the vicinity of Santa Rosa; Valencia County, New Mexico, along the lower part of the Rio San Jose; and Cibola County, New Mexico, in the vicinity of Grants. There are 3 sites in the Fort Stockton-Balmorhea area, 11 in the Dexter to Roswell area, 8 in the Santa Rosa area, 1 along the lower Rio San Jose, and 2 in the Grants area.

Most of the Pecos sunflower sites are limited to less than 2.0 hectares (ha) (5.0 acres (ac)) of wetland habitat with some being only a fraction of a hectare. Two sites, one near Fort Stockton and one near Roswell, are considerably more extensive. The number of plants per site varies from less than 100 to several hundred thousand for the 2 more extensive sites. Because Pecos sunflower is an annual, the number of plants per site can fluctuate greatly from year to year with changes in water conditions. Pecos sunflower is totally dependent on the persistence of its wetland habitat for even large populations will disappear if the wetland dries out.

Various Federal, State, Tribal, municipal, and private interests own and manage the Pecos sunflower sites. Managing Federal agencies include the Service, Bureau of Land Management,

and National Park Service. Plants are located on one New Mexico State park. Plants are located on municipal property within the cities of Roswell and Santa Rosa. The Laguna Indian Tribe owns and manages one site. Seven different private individuals or organizations own sites or parts of sites. Some plants grow on State or Federal highway rights-of-way.

Five sites are on property managed principally for wildlife and endangered species conservation. Two major sites are on Bitter Lake National Wildlife Refuge near Roswell, New Mexico. The refuge has a series of 6 spring-fed impoundments totaling about 300 ha (750 ac). These impoundments are managed with high water levels in winter followed by a spring and summer drawdown that simulates a natural water cycle. This regime provides abundant habitat for Pecos sunflower that grows in almost solid stands at the edge of some impoundments. There is a small site with less than 100 plants on Dexter National Fish Hatchery near Dexter, New Mexico. Plants first appeared here several years ago after saltcedar was removed to restore a wetland.

The Nature Conservancy of Texas owns and manages two sites, one near Fort Stockton, Texas, and the other near Balmorhea, Texas. Large desert springs are the principal features of both preserves. The spring near Fort Stockton harbors two species of endangered fish and three species of endemic snails, plus a large Pecos sunflower population that extends for about 1.2 kilometers (km) (0.75 miles (mi)) along the spring run. Two springs near Balmorhea, purchased in 1997, harbor a species of endangered fish and a population of several thousand Pecos sunflowers (Karges 1998).

The loss or alteration of wetland habitats is the main threat to Pecos sunflower. The lowering of water tables through aquifer withdrawals for irrigated agriculture; diversion of water from wetlands for irrigation, livestock, or other uses; wetland filling; and invasion of saltcedar and other non-native species continues to destroy or degrade desert wetlands. Mowing of some municipal properties and highway rights-of-way regularly destroys some plants. Livestock will eat Pecos sunflowers, particularly if other green forage is scarce. There was some unregulated commercial sale of Pecos sunflowers in the past and some plant collection for breeding programs to improve commercial sunflowers. Pecos sunflower will naturally hybridize with common sunflower. There is concern about the extent to which backcrosses

from hybrids could affect the genetic integrity of small Pecos sunflower populations.

#### Previous Federal Action

Federal government actions on Pecos sunflower began with section 12 of the Act, which directed the Secretary of the Smithsonian Institution to prepare a report on plants considered to be endangered, threatened, or extinct in the United States. The presentation of this report, designated as House Document No. 94-51, occurred on January 9, 1975. On July 1, 1975, we published a notice in the **Federal Register** (40 FR 27823) accepting the report as a petition within the context of section 4(c)(2) (now section 4(b)(3)(A)) of the Act and announcing our intent to review the status of the plants in the report. As a consequence of this review, we published a proposed rule in the **Federal Register** on June 16, 1976 (41 FR 24523), to designate approximately 1,700 vascular plants as endangered species. A final rule on the proposal had not been published in 1978 when new amendments to the Act required that all proposals over 2 years old be withdrawn with a 1-year grace period provided for proposals already over 2 years old. We published a **Federal Register** notice on December 10, 1979 (44 FR 70796), withdrawing the June 16, 1976, proposed rule in addition to four other previously expired proposals.

On December 15, 1980 (45 FR 82480), we published an updated notice of review of plants being considered for endangered or threatened designation. This notice included *Helianthus paradoxus* as a category 1 species, which are those species for which we had on file substantial information on biological vulnerability and threats to support proposals to designate them as endangered or threatened. We retained *Helianthus paradoxus* as a category 1 species in subsequent notice of review of plants published in the **Federal Register** on September 27, 1985 (50 FR 39526), February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51143). Beginning with our February 28, 1996, candidate notice of review (61 FR 7596), we discontinued the designation of multiple categories of candidates, and only those taxa meeting the definition of former category 1 candidates are now considered candidates for listing purposes. We retained *Helianthus paradoxus* as a candidate species in our September 19, 1997, candidate notice of review (62 FR 49398).

Section 4(b)(3)(B) of the Act requires the Secretary to make findings on pending petitions within 12 months of their receipt. Section 2(b)(1) of the 1982

amendments further requires that all petitions pending on October 13, 1982, be treated as though they were newly submitted on that date. This was the case for *Helianthus paradoxus* because of the acceptance of the 1975 Smithsonian report as a petition. On October 13, 1983, we made a petition finding that the listing of *Helianthus paradoxus* was warranted, but precluded by other pending listing actions, in accordance with section 4(b)(3)(B)(iii) of the Act. Notice of this finding was published on January 20, 1984 (49 FR 2485). A warranted but precluded finding requires that the petition be recycled pursuant to section 4(b)(3)(C)(i) of the Act. This finding was reviewed annually from 1984 through 1997. Publication of a proposed rule in the **Federal Register** on April 1, 1998 (63 FR 15808), to designate *Helianthus paradoxus* as a threatened species constituted the final 1-year finding for the petitioned action.

On June 15, 1998, we published a notice in the **Federal Register** (63 FR 32635) announcing the reopening the comment period and the location of public hearings on the proposal. We held public hearings on July 8, 9, and 13, 1998.

The processing of this final rule conforms with our Listing Priority Guidance for Fiscal Years 1998 and 1999, published on May 8, 1998 (63 FR 25502). The guidance clarifies the order in which we will process rulemakings giving highest priority (Tier 1) to processing emergency rules to add species to the Lists of Endangered and Threatened Wildlife and Plants (Lists); second priority (Tier 2) to processing final determinations on proposals to add species to the Lists, processing new listing proposals, processing administrative findings on petitions (to add species to the Lists, delist species, or reclassify listed species), and processing a limited number of proposed and final rules to delist or reclassify species; and third priority (Tier 3) to processing proposed and final rules designating critical habitat. Processing this final rule is a Tier 2 action.

#### Summary of Comments and Recommendations

In our April 1, 1998, proposed rule and associated notifications, we solicited interested parties to submit factual reports or information to contribute to the development of a final rule. In addition, contacts were made and we solicited comments from appropriate State and Federal agencies and representatives, Tribal governments, county governments,

municipal governments, scientific organizations, and other interested parties. We published legal notices soliciting comments in five newspapers—*Albuquerque Journal* on April 6, 1998, *Cibola County Beacon*, Grants, New Mexico, on April 8, 1998, *Santa Rosa News* on April 8, 1998, *Roswell Daily Record* on April 6, 1998, and *The Pioneer*, Fort Stockton, Texas, on April 8, 1998. In response to these notices we received several requests for a public hearing. On June 15, 1998 (63 FR 32635), we published a notice in the **Federal Register** announcing the dates and times for three scheduled public hearings, and notifying the public of the extension of the comment period until August 13, 1998. Newspaper notices announcing the public hearings and extended comment period appeared in the five newspapers listed above between June 24 and 26, 1998.

We received 14 written comments on the proposal. Seven commentors supported the proposed listing; these included two peer reviewers who also provided pertinent information included within this final rule, two State agencies, and three individuals. Seven commentors opposed the proposed listing; these included one State agency, one Indian Tribe, two private organizations, and three individuals.

We received requests to hold a public hearing requests from the New Mexico Farm and Livestock Bureau; New Mexico County Farm and Livestock Bureaus in Colfax, Cibola-McKinley, and Santa Fe counties; Production Credit Association of New Mexico; Texas and Southwestern Cattle Raisers Association; and Davis Mountains Trans-Pecos Heritage Association. We held hearings on the proposed rule on July 8, 9, and 13, 1998, at Fort Stockton, Texas; Roswell, New Mexico; and Grants, New Mexico at which a total of 34 people attended. Of the five oral statements presented at the hearings, one statement supported the listing, two opposed the listing, and two were neutral.

The following summary contains our response to the written comments we received during the comment period and to oral statements made during the public hearings. Comments on a similar topic are grouped by general issues.

**Issue 1:** Survey efforts were inadequate to find all Pecos sunflower populations. Because Pecos sunflower is a species of hybrid origin, survey efforts should encompass the entire range where the two parental species overlap, which includes the plains region from Canada to Mexico.

**Response:** The sunflowers are in a large genus with species distributed throughout North America. The taxonomy and distribution of these species has always attracted considerable interest, particularly the annual species most closely related to commercial sunflowers. Dr. Charles Heiser and his colleagues thoroughly investigated the annual sunflowers, examining thousands of specimens from 41 herbaria in the United States and Canada (Heiser *et al.* 1969). They found no specimens of Pecos sunflower other than those from near Fort Stockton, Texas, and the Rio San Jose in New Mexico. Other investigators such as Dr. Gerald Seiler of the U.S. Department of Agriculture, Dr. R.C. Jackson of Texas Tech University, and Dr. Loren Rieseberg of Indiana University studied sunflowers throughout North America for years without finding Pecos sunflower beyond its present known range. Our present knowledge of the distribution and abundance of Pecos sunflower relies, in part, on the work of these earlier investigators.

The Pecos sunflower is a large plant with bright yellow flowers that often grows in patches of thousands. Because its habitat is very specific and limited, it is unlikely that significant populations still remain unsurveyed after recent intensive efforts to survey for this species. However, even if other populations are found, they are likely to be subject to the same threats as the known populations.

**Issue 2:** Listing is unwarranted until a determination is made regarding the species' population ecology, pollinators, seed dispersers, seed viability, seed germination, and seed bank.

**Response:** While a comprehensive understanding of the life history and ecology of a species is useful when available, that level of knowledge is not required for listing. Listing a species as threatened or endangered is based on the five factors given in section 4(a)(1) of the Act. These factors and their application to Pecos sunflower are discussed in the "Summary of Factors Affecting the Species" section of this final rule.

**Issue 3:** Evidence indicates that Pecos sunflower has always been a rare species with numbers that fluctuate with yearly water conditions. There is no documentation that the species is either significantly increasing or declining in the region as a whole. Listing is unwarranted until a determination is made on the status of the species.

**Response:** Declines in rare plant species can be difficult to document when there are relatively few historical

collections and the localities provided with the specimens are imprecise. However, several of the specimens collected in Pecos County, Texas, strongly indicate Pecos sunflower once grew in places where it no longer occurs. The site 11 kilometers (or 7 miles (mi)) west of Fort Stockton where the type specimen (location of the population from which the plant was first described as a species) was collected in 1947 was reported to still have a remnant population in 1980 (Seiler *et al.* 1981), but since that time there are no reported findings of Pecos sunflowers. A specimen from "Fort Stockton" collected in 1943, is thought to be from around Comanche Springs, which is now dry and incapable of supporting Pecos sunflower. Although there is a reported collection from Escondido Creek occurring in the 1800s, the springs feeding this creek have been dry for many years, are no longer suitable habitat, and are no longer marked on topographic maps. One of the public hearing attendees who ranches in the Diamond Y area gave his recollection from 1949 of seeing a continuous stand of Pecos sunflowers along the then spring-fed draw (natural drainage basin) that runs into Diamond Y draw. The draw is now dry except for intermittent flows and Pecos sunflowers are absent.

These records and statements provide good evidence the distribution and abundance of Pecos sunflower has declined in West Texas with the loss of spring-fed wetlands. The collection record is inadequate to document similar declines in New Mexico, but they are likely due to the alteration and loss of wetlands.

**Issue 4:** There is no data indicating that livestock grazing is contributing to the decline of this species. The population on private land at Diamond Y Spring is grazed showing Pecos sunflower can co-exist with grazing.

**Response:** In the proposed rule we identified livestock grazing as a threat to Pecos sunflower by stating, "Livestock will eat Pecos sunflowers, particularly when other green forage is scarce." In the only study of grazing effects on the species, Bush and Van Auken (1997) found no significant differences between plants inside and outside cattle enclosures during a 1-year study. However, they are also careful to note that "This experiment was completed during a relatively wet year, and perhaps there was enough forage available for the herbivores. In subsequent years during times of drought, we have observed severe herbivory of *H. paradoxus* and extreme differences in the stem length and



number of flowers (unpublished). Therefore, the effects of large grazers of *H. paradoxus* may be dependent on the availability of moisture and its effects on the grazers preferred forage plants." This agrees with our (the Service's) observations of grazing on Pecos sunflower. It is possible to have grazing at Pecos sunflower populations, as evidenced by the Diamond Y Spring site, but good grazing management is still needed to prevent or reduce damage to the populations.

*Issue 5:* In addition to grazing by livestock, consider the effects of predation from wildlife species and insects. Additional studies are needed to determine elk damage to riparian areas in New Mexico.

*Response:* Although we have not seen significant wildlife or insect predation on Pecos sunflower, such impacts are possible. Insects and their damage to maturing seeds can go undetected because the plants may otherwise appear perfectly normal. Elk in New Mexico usually occur at much higher elevations than the Pecos sunflower populations.

*Issue 6:* Pecos sunflower can survive periods of natural drought. Threats associated with problem years having little or no rainfall should be attributed to natural causes.

*Response:* We agree droughts occur naturally and contribute to poor growing conditions for Pecos sunflower during some years. We consider natural factors affecting the species under Factor E of the "Summary of Factors Affecting the Species" section of this final rule. The Act directs us to consider both natural factors and human-caused threats in determining whether a species is endangered or threatened.

*Issue 7:* The statement that Pecos sunflowers grow on the dams of man-made impoundments appears to contradict the statement that the species is dependent on wetlands.

*Response:* We acknowledge that the statement that Pecos sunflowers plants grow on dams does need some clarification. Plants found on dams grow in saturated soils either at the shoreline or where there is seepage through the dam. Pecos sunflowers do not grow on the dry upland portion of a dam.

*Issue 8:* The focus on the loss of natural wetlands appears misplaced, especially when one of the largest known populations occupies created wetlands at Bitter Lake National Wildlife Refuge.

*Response:* Our discussion emphasizes the loss of natural wetlands because these losses exceed the rate of wetland creation. The wetlands created at Bitter Lake National Wildlife Refuge simply

replace former natural spring-fed wetlands and still rely on those springs for water. There is a high probability that Pecos sunflowers grew around the springs before the refuge impoundments were built.

*Issue 9:* Hybridization is a natural event and should not be considered a threat.

*Response:* Hybridization between Pecos sunflower and common sunflower may not be a totally natural occurrence. Substantial increases in the habitat of common sunflower can result from human land disturbances and the construction of road ditches. These disturbances have made it possible for common sunflower to grow much closer to Pecos sunflower than was possible in the past. Because of concerns about hybridization, personnel from the Texas Parks and Wildlife Department have been removing common sunflowers from the road ditches near the Pecos sunflower population at Texas Highway 18 north of Fort Stockton. Even if such hybridization was completely natural, we still must consider the effects of Pecos sunflower potentially hybridizing with other species under Factor E of the "Summary of Factors Affecting the Species" section of this final rule.

*Issue 10:* Because listing may increase collecting and vandalism through heightened attention to the species and because Pecos sunflowers will not be protected from collecting or destruction on private lands, listing will increase risks to the species rather than reducing them.

*Response:* We believe the conservation measures for listed species described in the "Available Conservation Measures" section of this final rule greatly outweigh any risks associated with listing. We are also minimizing those potential risks through our "not prudent" finding for the designation of critical habitat (see discussion under Critical Habitat, below) and through outreach and education directed towards individual private landowners.

*Issue 11:* Listing is not warranted because other management and protection measures are already removing threats to the species including: protective management on The Nature Conservancy's preserves and Bitter Lake National Wildlife Refuge, the presence of several federally listed fish species at some sites that already serve to protect the essential habitat, protection in New Mexico through State listing, a management agreement between the Texas Department of Transportation and the Texas Parks and Wildlife Department for the population on Texas Highway 18, and various

Federal agency policies that protect candidate species.

*Response:* While these measures are important for conservation, the threats to the species have not been reduced or removed so that listing is no longer necessary. We find that enough Pecos sunflower populations lack sufficient protection to warrant listing the species as threatened.

*Issue 12:* There are many conservation measures for Pecos sunflower that can be implemented without the need for Federal listing and these measures would be more effective than the protections provided under the Act. These include: State listing in Texas under chapter 88 of the Texas Parks and Wildlife Code; funding to hire a botanist to do surveys, develop a conservation strategy, and work with local landowners; horticultural propagation of Pecos sunflowers for introduction into unoccupied suitable habitats; purchase of lands through the New Mexico Natural Lands Protection Act or the Federal Land and Water Conservation Fund; development of a regional water plan for West Texas through recently passed State legislation; and conservation in the Rio Puerco watershed in New Mexico through a recently funded multi-agency watershed initiative.

*Response:* We must base our listing determinations on current threats. For example, the general obligation bond to provide funding for the New Mexico Lands Protection Act was defeated in a recent general election leaving no funds for land acquisition. Listing the species as threatened and the subsequent drafting of a recovery plan will increase the likelihood that agencies, organizations, and individuals will be able to accomplish conservation measures for this species. We encourage further implementation of conservation measures for the Pecos sunflower, and we will consider delisting the species when it becomes sufficiently protected and recovered to ensure its continued survival.

*Issue 13:* Because of the many actions on Tribal lands that are authorized, funded, or carried out by the Bureau of Indian Affairs, listing this species will place the largest section 7 consultation burden on the Laguna Tribe. This is contrary to the intent of Secretarial Order 3206 and Executive Order 13084 that strive to ensure Indian Tribes do not bear a disproportionate burden for the conservation of listed species.

*Response:* Because only one of the 25 known sites for Pecos sunflower occurs on Tribal lands, we anticipate that most activities for the conservation of Pecos sunflower will be undertaken by other

agencies, organizations, and individuals. The one site on Tribal lands probably occupies only a few acres and is in a remote undeveloped part of the reservation. It is unlikely there will be many actions at this site that will require section 7 consultation. If consultation is needed, we will seek to find ways to both conserve the listed species and complete the action. Our hope is that we can help Pecos sunflower to recover through voluntary efforts and cooperation with other Federal agencies, States, local and Tribal governments and private landowners and conservation groups.

**Issue 14:** Listing Pecos sunflower will have negative economic impacts on the farmers, ranchers, and communities where it occurs.

**Response:** We believe the listing of the Pecos sunflower as threatened will not force private landowners to change any existing land practices. We anticipate that any economic impacts of listing will be minimal due to the small number of populations that are involved. The Act requires listing determinations to be made solely on the basis of the best available scientific and commercial information regarding the species' status without reference to possible economic or other impacts of the determination. Economic considerations may only be considered in the designation of critical habitat and in recovery planning and implementation.

**Issue 15:** Designation of critical habitat would help farmers and ranchers manage the species by showing them where it occurs.

**Response:** As with every Federal listing, we conduct intensive outreach to inform landowners if the species occurs on their land. We believe that information about the location of populations is best handled through direct contact with individual landowners. The reasons for our "not prudent" finding for the designation of critical habitat are given in the "Critical Habitat" section of this final rule.

### Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. We determine a species to be endangered or threatened due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Helianthus paradoxus* Heiser (Pecos sunflower) are as follows:

#### *A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range*

Wetland habitats in the desert Southwest are both ecologically important and economically valuable. Wetlands cover only about 195,000 ha (482,000 ac) (0.6 percent) of New Mexico (Fretwell *et al.* 1996). This is a reduction of about 33 percent from the wetland acreage that existed 200 years ago (Dahl 1990). Wetlands in Texas cover 3,077,000 ha (7,600,000 ac), a decline of about 52 percent from the State's original wetland acreage (Dahl 1990). The loss of springs in western Texas may be a better indicator of wetland losses that affect Pecos sunflower than estimates for the State as a whole. Within the historical range of Pecos sunflower in Pecos and Reeves counties, only 13 of 61 (21 percent) springs remain flowing (Brune 1981 in Poole 1992).

The lowering of water tables due to groundwater withdrawals for irrigated agriculture, municipalities, and other uses has reduced available habitat for Pecos sunflower, particularly in Texas. Beginning around 1946, groundwater levels fell as much as 120 m (400 ft) in Pecos County and 150 m (500 ft) in Reeves County due to heavy pumping for irrigation. As a result, most of the springs in these counties have gone dry. Groundwater pumping has lessened in recent decades due to the higher cost of removing water from deeper aquifers in the ground, but rising water tables or resumption of spring flows are not expected (Brune 1981 in Poole 1992). Diamond Y Spring, which has a large Pecos Sunflower population, remains flowing largely because it comes from a saline strata unsuitable for agricultural or municipal uses.

Texas water law provides no protection for remaining springs. The law is based on the right of first capture that lets any water user pump as much groundwater as can be put to a beneficial use without regard to overall effects on the aquifer. Recently passed Texas legislation directs the development of regional water plans in the State, but it is too soon to know if this planning effort will have any beneficial effects for Pecos sunflower.

Groundwater pumping affected Pecos sunflower habitats in Chaves County, New Mexico, but water tables are now rising due to State-directed efforts at monitoring and conservation. These efforts are the result of a court ruling that requires New Mexico to deliver larger volumes of Pecos River water to Texas than in the past. There are presently no major groundwater

withdrawals taking place in the vicinity of the other Pecos sunflower sites in New Mexico.

The introduction of non-native species, particularly saltcedar, is a major factor in the loss and degradation of Southwestern wetlands. Several species of saltcedar were introduced into the United States for ornamental purposes as windbreaks, and as stream bank stabilization in the 1800s. Saltcedar and other non-native vegetation invaded many western riverine systems from the 1890s to the 1930s and increased rapidly from the 1930s to the 1950s, by which time they occupied most of the available and suitable habitat in New Mexico and western Texas (Horton 1977).

Saltcedar will out-compete and displace native wetland vegetation, including Pecos sunflower. At Dexter National Fish Hatchery, Pecos sunflower appeared for the first time in the summer of 1996 after saltcedar was removed to rehabilitate a wetland (Radke 1997). Saltcedar affects 2,000 ha (5,000 ac) at Bitter Lake National Wildlife Refuge where the most extensive Pecos sunflower population occurs (Service 1996). Although there have been many projects on refuges to remove saltcedar, these projects are labor intensive and reinvasion of saltcedar is a continuing problem.

We know that some wetlands where Pecos sunflower occurs have either been filled or impounded. Part of a wetland near Grants, New Mexico, was filled for real estate development along a major highway. The development predated knowledge that Pecos sunflower grows in the area, so it is unknown if any plants were actually destroyed. Present development in this area that could affect Pecos sunflower includes construction of a discount department store and other smaller shops, and reconstruction of a highway overpass.

Wetlands in Santa Rosa were lost many years ago to impoundment created for a fish hatchery that has since been abandoned. Pecos sunflowers grow in wet soils on some impoundment dams. Because the extent of this former wetland habitat is unknown, it is uncertain whether these impoundments have actually increased or decreased sunflower habitat.

Alteration of habitat is occurring by mowing on some highway rights-of-way and some municipal properties where Pecos sunflower occurs. In Santa Rosa, the weeds and some Pecos sunflowers are often mowed around some of the old fish hatchery ponds now used for recreational fishing. In another part of town an open boggy area is mowed when dry enough. In years when it is

too wet to mow, a stand of Pecos sunflowers develops. Mowing of highway rights-of-way in Santa Rosa and near Grants may be destroying some plants. In Texas, the only population in a highway right-of-way was fenced several years ago to protect it from mowing and other activities.

#### *B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes*

Some commercial trade in Pecos sunflower has occurred in the past (Poole, Texas Parks and Wildlife Department, Austin, *in litt.* 1991). This trade was undertaken by an organization interested in preserving rare species of indigenous crop plants through their distribution and cultivation. There was also some collecting for crop breeding research (Seiler *et al.* 1981). With its tolerance for high salinity, Pecos sunflower is considered a good candidate for the introduction of salt tolerance into cultivated sunflowers. Some Pecos sunflower sites are both small and easily accessible. Repeated uncontrolled collecting may harm these sites.

#### *C. Disease or Predation*

Livestock eat Pecos sunflowers, particularly when other green forage is scarce. Livestock tend to pull off the flower heads. If an area is heavily grazed for several years in succession when plants are flowering, the soil seed bank may diminish and the population will eventually decline. There are several examples of Pecos sunflowers being absent from habitat that is heavily grazed, but growing in similar nearby habitat that is protected from grazing. In these instances, grazing is the most likely cause of the plant's absence from otherwise suitable habitat. There are also examples of Pecos sunflower populations persisting in areas grazed for many years. Apparently the type and intensity of grazing has much to do with the persistence of Pecos sunflower in these areas. There have been no observations of wildlife grazing or insect damage on Pecos sunflower.

#### *D. The Inadequacy of Existing Regulatory Mechanisms*

Pecos sunflower is listed as a New Mexico State endangered plant species in NMNRD Rule 85-3 of the State Endangered Plant Species Act (9-10-10 NMSA). The scientific collection, commercial transport, and sale of Pecos sunflower is already regulated by NMSA. However, NMSA does not protect habitat on private land or require collecting permits for Federal employees working on lands within

their jurisdictions (Sivinski and Lightfoot 1995). The penalty for violating NMSA is a misdemeanor carrying a fine of not more than \$1,000 and/or incarceration for not more than 120 days; by comparison, the criminal penalty for violation of the Federal Act carries a fine of not more than \$50,000 and/or imprisonment for not more than 1 year, a much greater deterrent than that available under State law. In general, State listing fails to generate the level of recognition or promote the opportunities for conservation that result through Federal listing. Most importantly, NMSA lacks the interagency coordination and conservation requirements found in section 7 of the Federal Act. Pecos sunflower is not listed as an endangered, threatened, or as a protected plant under the Texas Endangered Plant Species Act.

#### *E. Other Natural or Manmade Factors Affecting Its Continued Existence*

Natural hybrids between Pecos sunflower and common sunflower can occur and are known from sites in both Texas and New Mexico. Habitat for common sunflower is increased by human activities and the two sunflowers may be in greater contact than in the past. Natural hybrids have low fertility, but are not completely sterile (Heiser 1965). A measure of isolation between the two species is provided by the different flowering times for Pecos sunflower and common sunflower. Hybrids are likely to be intermediate between the two species in flowering time and may serve as a bridge for gene flow between the species. Once a bridge is established, the genetic swamping of small Pecos sunflower populations could occur rapidly.

Natural droughts are common in the desert regions where Pecos sunflower occurs. These droughts combined with the effects of wetland alterations and losses could extirpate some small populations. The present distribution of Pecos sunflower coincides with areas having large reliable springs and this may in part be a response to the effects of natural droughts.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to issue this final rule. Based on this evaluation, our preferred action is to list Pecos sunflower as a threatened species. The drying of springs due to ground water pumping, the diversion of water for agriculture and other uses, the filling of wetlands, the degradation of wetlands from

intensive livestock grazing, and the invasion of saltcedar and other non-native plants into many wetlands has significantly reduced the habitat of this species. Most remaining populations are vulnerable because these and other activities continue to destroy habitat or keep it in a degraded condition. While not in immediate danger of extinction, the Pecos sunflower is likely to become an endangered species in the foreseeable future if present trends continue.

#### **Critical Habitat**

Section 3 of the Act defines critical habitat as—(i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management consideration or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for conservation of the species. "Conservation" means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be endangered or threatened. We find that designation of critical habitat is not prudent for Pecos sunflower. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist—(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

Critical habitat designation for Pecos sunflower is not prudent for both of the above reasons. There has been some commercial trade in Pecos sunflower, which was due largely to its rarity (See Factor B of the "Summary of Factors Affecting the Species" section). There are several documented instances of other species of commercially valuable rare plants being collected when their localities became known. In 1995, at least 48 plants of the endangered *Pediocactus knowltonii* (Knowlton cactus) were taken from a monitoring plot at the species' only known locality (Sivinski, New Mexico Forestry

Division, Santa Fe, *in litt.* 1996). In the early 1990s, the rediscovery of *Salvia penstemonoides* (big red sage) in Texas led to the collection of thousands of seeds at the single rediscovery site (Poole, *in litt.* 1991).

Listing contributes to the risk of over collecting because the rarity of a plant is made known to far more people than were aware of it previously. Designating critical habitat, including the required disclosure of precise maps and descriptions of critical habitat, would further advertise the rarity of Pecos sunflower and provide a road map to occupied sites causing even greater threat to this plant from vandalism or unauthorized collection. Many of the Pecos sunflower sites are small, have few individuals, and are easily accessible. These sites would be particularly susceptible to indiscriminate collection if publication of critical habitat maps made their exact locations known.

Critical habitat designation, by definition, directly affects only Federal agency actions. Private interests own 13 of the 25 Pecos sunflower sites. For the most part, activities constituting threats to the species on these lands, including alterations of wetland hydrology, competition from non-native vegetation, grazing, and agricultural and urban development, are not subject to the Federal review process under section 7. Designation of critical habitat on private lands provides no benefit to the species when only non-Federal actions are involved.

Activities on Federal lands and some activities on private lands require Federal agencies to consult with us under section 7. There are few known sites for Pecos sunflower and habitat for the species is limited. Given these circumstances, any activity that would adversely modify designated critical habitat would likely also jeopardize the species' continued existence. Thus, in this case, the Federal agency prohibition against adverse modification of critical habitat would provide no additional benefit beyond the prohibition against jeopardizing the species.

Occupied habitat for Pecos sunflower occurs on a National Wildlife Refuge and a National Fish Hatchery, which we administer; a National Monument the National Park Service administers, and public lands the Bureau of Land Management administers. Because these occupied habitats are well known to these Federal land managers, no adverse modification of this habitat is likely to occur without consultation under section 7 of the Act. Because of the small size of the species' habitat, any adverse modification of the species'

critical habitat would also likely jeopardize the species' continued existence. Designation of critical habitat for Pecos sunflower on Federal lands, therefore, is not prudent because it would provide no additional benefit to the species beyond that conferred by listing.

#### Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The elevated profile Federal listing affords enhances the likelihood that conservation activities will be undertaken. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to species that are listed or proposed for listing as endangered or threatened and with respect to those species' designated or proposed critical habitat, if any. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat.

If a Federal action may adversely affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us. Federal agencies that manage occupied Pecos sunflower habitat are the ones most likely to have activities that involve section 7 consultation. These agencies are the Bureau of Land Management, National Park Service, and Fish and Wildlife Service. Other agencies with potential section 7 involvement include the U.S. Army Corps of Engineers through its permit authority under section 404 of the Clean

Water Act, the Natural Resources Conservation Service that provides private landowner planning and assistance for various soil and water conservation projects, the Federal Highway Administration for highway construction and maintenance projects that receive funding from the Department of Transportation, the Bureau of Indian Affairs that has trust responsibilities for certain activities on Indian lands, and various agencies of the Department of Housing and Urban Development that undertake homeowner mortgage insurance and community development programs.

We considered the potential impacts of designating Pecos sunflower as a threatened plant species in relation to the compliance of this action with Secretarial Order 3206. That order was issued to clarify the responsibilities of the component agencies, bureaus, and offices of the Department of the Interior and the Department of Commerce, when actions taken under authority of the Act and associated implementing regulations affect, or may affect, Indian lands, Tribal trust resources, or the exercise of American Indian Tribal rights. In keeping with the trust responsibility and government-to-government relationships, we recognize our responsibility to consult with affected Tribes and provide written notice to them as far in advance as practicable of conservation restrictions that we consider necessary to protect listed species.

Secretarial Order 3206 states that, "If a proposed conservation restriction is directed at a Tribal activity that could raise the potential issue of direct (directed) take under the Act, then meaningful government-to-government consultation shall occur, in order to strive to harmonize the Federal trust responsibility to Tribes, Tribal sovereignty and the statutory missions of the Department of Interior and Commerce." The term "take" as defined in the Act means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. The Act has no prohibitions against take for listed plants; instead, regulations for threatened plants found at 50 CFR 17.71 prohibit their removal or reduction to possession from areas under Federal jurisdiction. For threatened plants, there are no prohibitions against their removal and reduction to possession from areas outside Federal jurisdiction or against their damage or destruction in any area when no removal and reduction to possession are involved. We know of no instance where Indian Tribal members collect (*i.e.* remove and

reduce to possession) Pecos sunflowers for cultural, spiritual, religious, or economic reasons. Therefore, we do not believe the prohibition against removal or reduction to possession from areas under Federal jurisdiction will affect Indian lands, Tribal trust resources, or the exercise of American Indian Tribal rights.

We met with representatives of the Laguna Tribe on March 12, 1998, prior to publication of the listing proposal to discuss our intention to propose Pecos sunflower for protection under the Act. We discussed with them range-wide threats to the species, conservation measures listing would initiate, prohibitions that would result from listing, Tribal activities that occur in the area where the sunflower grows on Tribal lands, and the role of Federal agencies (especially the BIA) in insuring that activities they authorize, fund, or carry out do not jeopardize the continued existence of listed species. We discussed the value of monitoring to assess conservation needs and indicated we would provide whatever assistance we could for monitoring and a conservation program on Tribal lands. Subsequently, we were contacted by a Tribal representative to provide whatever information we had concerning Pecos sunflower. We went through our files with the representative and supplied those documents thought useful to the Tribe. We kept the Tribe informed during the listing proposal process with notifications about proposal comment requests and public hearings.

A question was raised concerning the potential effect listing this plant might have on future Indian water rights claims. The Pecos sunflower on Tribal lands occurs at springs adjacent to the Rio San Jose. These springs, although near the river, are not dependent on it for their flows. If upstream water rights claims reduced flows in the Rio San Jose, the sunflower would likely be unaffected. The area where the springs occur is presently used for grazing. The Tribe indicates no planned land use changes that would create new demands on water from the springs. Finally, if any water use changes led to loss of the sunflower on Tribal lands it would not violate any of the limited prohibitions applicable to threatened plants given in section 9 of the Act or in 50 CFR 17.71. Water use changes occurring on non-Federal lands and having no Federal nexus would also not be subject to the requirements of section 7 of the Act. Given these conditions, we cannot foresee a circumstance where listing Pecos sunflower as a threatened plant would affect Indian water rights claims.

Listing Pecos sunflower will require us to develop a recovery plan to help coordinate Federal, State, and private efforts to conserve this species. The plan will establish a framework for agencies to coordinate activities and cooperate in conservation efforts. The plan will set recovery priorities, estimate costs of various tasks, and describe site-specific management actions necessary to achieve conservation and survival of the species. Additionally, under section 6 of the Act, we will be able to grant funds to the states of New Mexico and Texas for management actions promoting the protection and recovery of Pecos sunflower.

Because many of the known Pecos sunflower sites are on private land, we will pursue conservation easements and conservation agreements with willing private landowners to help maintain and/or enhance habitat for the plant. Under a cooperative program between us and the State of New Mexico, contacts were made with all private landowners and the importance of Pecos sunflower and the consequences for the private landowner of having it listed under the Act explained. To date, no agreements are established but several landowners indicate a willingness to continue with discussions.

The Act and its implementing regulations found at 50 CFR 17.71 and 17.72 set forth a series of general prohibitions and exceptions that apply to all threatened plants. All trade prohibitions of Section 9(a)(2) of the Act, implemented by 50 CFR 17.71, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale this species in interstate or foreign commerce, or to remove and reduce to possession the species from areas under Federal jurisdiction. Seeds from cultivated specimens of threatened plants are exempt from these prohibitions provided that their containers are marked "Of Cultivated Origin." Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies.

The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened plant species under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation or survival of the species. For threatened plants, permits are also available for botanical or horticultural exhibition, educational purposes, or

special purposes consistent with the purposes of the Act.

Pecos sunflower is uncommon both in cultivation or in the wild, and there was only limited commercial trade in the species. Therefore, it is anticipated few trade permits will ever be sought or issued. You should direct requests for copies of the regulations concerning the trade of listed plants and general inquiries regarding prohibitions and permits to the U.S. Fish and Wildlife Service (see ADDRESSES section). Information collections associated with these permits are approved under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and assigned Office of Management and Budget clearance number 1018-0094. For additional information about these permits and associated requirements, see 50 CFR 17.72.

It is our policy (59 FR 34272; July 1, 1997) to identify to the maximum extent practicable at the time we list a species those activities that would or would not constitute a violation of the section 9 prohibitions of the Act. The intent of this policy is to increase public awareness of the effect of this listing on proposed and ongoing activities within the species' range. You may take the following actions, without violation of section 9, when carried out in accordance with existing regulations and permit requirements:

(1) Activities authorized, funded, or carried out by Federal agencies (e.g., wetland modification; the construction or maintenance of drainage ditches, construction of impoundments or other livestock watering facilities, power line construction, maintenance, and improvement; highway construction, maintenance, and improvement; mineral exploration and mining,) when such activity is conducted in accordance with any reasonable and prudent measures given by us according to section 7 of the Act. These activities may require Federal, State, and/or local approval under other laws or regulations.

(2) Normal agricultural practices, including mowing or clearing, and light to moderate livestock grazing, and pesticide and herbicide use, carried out in accordance with any existing regulations, permit and label requirements, and best management practices.

(3) Clearing a defensible space for fire protection and normal landscape activities around one's personal residence.

We believe that the following might potentially result in a violation of section 9; however, possible violations are not limited to these actions alone:

(1) Removal, cutting, digging up, damaging, or destroying threatened plants on non-Federal land if conducted in knowing violation of State law or regulation or in violation of State criminal trespass law.

(2) Interstate or foreign commerce and import/export without previously obtaining an appropriate permit.

(3) The unauthorized removal, reducing to possession or collection of this species from areas under Federal jurisdiction.

In appropriate cases, permits could be issued to allow collection for scientific or recovery purposes, for horticultural or botanical exhibition, for educational purposes, or for special purposes consistent with the purposes of the Act. You should direct questions regarding whether specific activities may constitute a violation of section 9 to the Field Supervisor of the New Mexico Ecological Services Field Office (see ADDRESSES section).

#### National Environmental Policy Act

We have determined that Environmental Assessments and

Environmental Impact Statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

#### Required Determinations

This rule does not contain collections of information that require Office of Management and Budget approval under 44 U.S.C. 3501 *et seq.*

#### References Cited

A complete list of all references cited herein is available on request from the U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office (see ADDRESSES section).

Author: The primary author of this final rule is Charlie McDonald, New Mexico Ecological Services Field Office (see ADDRESSES section).

#### List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

#### Regulation Promulgation

#### PART 17—[AMENDED]

Accordingly, the Service amends part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

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

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.12(h) add the following to the List of Endangered and Threatened Plants in alphabetical order under FLOWERING PLANTS:

#### § 17.12 Endangered and threatened plants.

\* \* \* \* \*

(h) \* \* \*

Species			Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name							
FLOWERING PLANTS								
*	*	*	*	*		*		*
Helianthus paradoxus .....	Pecos sunflower (=puzzle sunflower, paradox sunflower).		U.S.A. (NM, TX) ...	Asteraceae .....	T	667	NA	NA
*	*	*	*	*		*		*

Dated: September 14, 1999.

**John G. Rogers,**

Acting Director, Fish and Wildlife Service.

[FR Doc. 99–27186 Filed 10–19–99; 8:45 am]

BILLING CODE 4310–55–P

#### DEPARTMENT OF THE INTERIOR

#### Fish and Wildlife Service

#### 50 CFR Part 17

RIN 1018–AE57

#### Endangered and Threatened Wildlife and Plants; Final Rule to List *Astragalus desereticus* (Deseret milk-vetch) as Threatened

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), determine the plant species, *Astragalus desereticus* (Deseret milk-vetch), to be a threatened species under the authority of the

Endangered Species Act of 1973, as amended (Act). *Astragalus desereticus*, considered extinct until its rediscovery in 1981, exists in one small population in Utah County, Utah. Threats to the plant include residential development, highway widening, livestock grazing and trampling, and other impacts to its limited habitat. This plant receives no protection under State or local laws or regulations. This rule implements Federal protection provided by the Act for this plant.

**EFFECTIVE DATE:** November 19, 1999.

**ADDRESSES:** The complete file for this rule is available for public inspection, by appointment, during normal business hours at the Utah Ecological Services Field Office, U.S. Fish and Wildlife Service, Lincoln Plaza Suite 404, 145

East 1300 South, Salt Lake City, Utah 84115.

**FOR FURTHER INFORMATION CONTACT:** John L. England at the above address (telephone: 801/524–5001).

#### SUPPLEMENTARY INFORMATION:

#### Background

Marcus E. Jones collected a distinctive *Astragalus* from “below Indianola,” a town in Sanpete County, Utah, on June 2, 1893. This same plant was again collected by Ivar Tidestrom from “near Indianola” on June 17, 1909. Specimens from these two collections laid in obscurity in various herbaria until Rupert Barneby recognized their uniqueness and described them as *Astragalus desereticus* (Barneby 1964). Efforts to relocate the species’

population were initially fruitless (Barneby 1964, Welsh 1978a, 1978c) leading to a presumption of extinction (Ripley 1975, Welsh 1975, 1978b). However, on May 27, 1981, Elizabeth Neese discovered a population of *A. desereticus* on a sandstone outcrop above the town of Birdseye, Utah County, Utah, less than 6.2 kilometers (km) (10 miles (mi)) from Indianola (Welsh and Chatterley 1985). This population remains the only known occurrence of the species (Franklin 1990, 1991, Service 1991). It is possible that this population is the one from which Jones and/or Tidestrom made their collections more than 70 years earlier (Franklin 1990, 1991, Welsh and Chatterley 1985).

*Astragalus desereticus* is a perennial, herbaceous, sub-acaulous (almost stemless) plant in the bean family (*Fabaceae*). Individual plants are approximately 4–15 centimeters (cm) (2–6 inches (in)) in height, and arise from a caudex (the persistent base of an otherwise annual herbaceous stem). Stems are about 6 cm (2 in) tall. The pinnately compound leaves (feather-like arrangement with leaflets displayed on a central stalk) are 4–11 cm (2–4 in) long with 11–17 leaflets. The leaflets are elliptic to ovate in shape, with a dense silvery gray pubescence (short hairs) on both sides. The species' flowers are of the characteristic papilionaceous form common to the bean family, 1.8–2.2 cm (0.7–0.9 in) long, white in color with a purple tip on the keel, and borne on a stalk of 5–10 flowers. The seed pods are 1 to 2 cm (0.4–0.8 in) long, densely covered with lustrous hairs, and bear 14–16 ovules (a minute rudimentary structure from which a plant seed develops after fertilization). Detailed descriptions of *A. desereticus* can be found in Barneby (1964, Barneby in Cronquist *et al.* 1989), and in Welsh (1978c, Welsh *et al.* 1987, 1993).

The only known population of *Astragalus desereticus* occurs primarily on steep south- and west-facing slopes. The plant grows on soils derived from a specific and unusual portion of the geologic Moroni Formation. This geologic feature is characterized by coarse, crudely bedded conglomerate (Franklin 1990). The plant community in which *A. desereticus* occurs is dominated by pinon pine (*Pinus edulis*) and Utah juniper (*Juniperus osteosperma*). Other associated plant species include: sagebrush (*Artemisia tridentata*), scrub oak (*Quercus gambelii*), wild buckwheat (*Eriogonum brevicaule*), Indian ricegrass (*Stipa hymenoides*), needle and thread grass (*Stipa comata*), bitter brush (*Purshia*

*tridentata*), and plateau beardtongue (*Pentstemon scariosus*) (Franklin 1990).

The sole population of *Astragalus desereticus* consists of between 5,000 and 10,000 individuals that grow on an area of less than 120 hectares (ha) (300 acres (ac)) (Franklin 1990, Stone 1992). The species' total range is approximately 2.6 km (1.6 mi) long, and 0.5 (km) (0.3 mi) across. Extensive searches of similar habitat in Utah and Sanpete Counties, Utah, have failed to identify any other populations (Franklin 1991, Larry England, Service, pers. comm. 1997). The land upon which *A. desereticus* grows is owned by the State of Utah and three private land owners (Franklin 1990, 1991; Chris Montague, The Nature Conservancy, 1992, 1997 pers. comm.). *Astragalus desereticus* is threatened by grazing and trampling by ungulates, alteration of its habitat due to residential development and road widening, and natural events, such as fire, due to its limited distribution.

#### Previous Federal Action

Section 12 of the Act (16 U.S.C. 1531 *et seq.*) directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. The Secretary presented this report, designated as House Document No. 94–51, to Congress on January 9, 1975. On July 1, 1975, we published a notice in the **Federal Register** (40 FR 27823) accepting the report as a petition to list those taxa named therein under section 4(c)(2) of the Act (petition acceptance is now governed by section 4(b)(3) of the Act), and its intention to review the status of those plants. *Astragalus desereticus* was included in the July 1, 1975, notice on list "C," indicating that the species was probably extinct.

On June 16, 1976, we published a proposed rule in the **Federal Register** (41 FR 24523) to designate approximately 1,700 vascular plant species, including *Astragalus desereticus*, as endangered pursuant to section 4 of the Act. The Smithsonian Institution and the Service assembled this list of 1,700 plant species on the basis of comments and data received in response to House Document No. 94–51 and the July 1, 1975, **Federal Register** publication. In the proposed rule, we also designated *A. desereticus* as a species about which we were particularly interested in obtaining any new information on living specimens and extant populations. General comments received in relation to the 1976 proposal are summarized in an April 26, 1978, **Federal Register** publication (43 FR 17909). The 1978 amendments to the Act required that all

proposals over 2 years old be withdrawn, although proposals published before the 1978 amendments' enactment could not be withdrawn before the end of a 1-year grace period beginning on the enactment date. On December 10, 1979, we published a notice of withdrawal (44 FR 70796) of that portion of the June 16, 1976, proposal that had not been made final, which included *A. desereticus*.

On December 15, 1980, we published a revised notice of review for native plants in the **Federal Register** (45 FR 82480) designating *Astragalus desereticus* a category 1 species. At that time, we defined category 1 candidates as those taxa for which we had on file sufficient information on biological vulnerability and threats to support preparation of listing proposals. In addition, *A. desereticus* was identified as a species that may have recently become extinct. In 1981, a population of *A. desereticus* was discovered. On November 28, 1983, we published a revised notice of review in the **Federal Register** (48 FR 53640) in which *A. desereticus* was included as a category 2 candidate species. Category 2 candidates were formally defined as taxa for which data on biological vulnerability and threats indicated that listing was possibly appropriate, but for which data were not sufficient to support issuance of listing proposals. In preparing the 1983 notice, we deemed it appropriate to acquire additional information on the distribution and abundance of *A. desereticus* before proposing the species for listing. We maintained *A. desereticus* as a category 2 species in updated notices of review published in the **Federal Register** on September 27, 1985 (50 FR 39526), and February 21, 1990 (55 FR 6184). As a result of additional information obtained in 1990 and 1991 status surveys (Franklin 1990 and Service 1991), we reclassified *A. desereticus* as a category 1 candidate in the September 30, 1993, notice of review (58 FR 51144). Upon publication of the February 28, 1996, Notice of Review, (61 FR 7596), we ceased using category designations and included *A. desereticus* as a candidate species. Candidate species are those for which the Service has on file sufficient information on biological vulnerability and threats to support proposals to list the species as threatened or endangered. We maintained *Astragalus desereticus* as a candidate in the September 19, 1997, Notice of Review (62 FR 49398).

Section 4(b)(3)(B) of the Act's 1982 amendments required the Secretary of the Interior to make findings on certain petitions within 1 year of their receipt.



Section 2(b)(1) of the Act's 1982 amendments further required that all petitions pending as of October 13, 1982, be treated as having been newly submitted on that date. Because we accepted the 1975 Smithsonian report and the Service's notices as petitions, we treated all the taxa contained in those notices, including *Astragalus desereticus*, as having been newly petitioned on October 13, 1982. The deadline for a finding on such petitions, including that for *A. desereticus*, was October 13, 1983. Since that date, we made successive 1-year findings that listing *A. desereticus* was warranted, but precluded by other listing actions of higher priority. Our proposal to list *A. desereticus* as threatened on January 28, 1998 (63 FR 4207), constituted the warranted 12-month finding for this species.

The processing of this final rule conforms to our Listing Priority Guidance for Fiscal Years 1998 and 1999 published in the **Federal Register** on May 8, 1998 (63 FR 25502). The guidance clarifies the order in which we will process rulemakings. Highest priority is processing emergency listing rules for any species determined to be facing a significant and imminent risk to its well being (Tier 1). Second priority (Tier 2) is processing final determinations on proposed additions species to the lists of endangered and threatened wildlife and plants; the processing of new proposals to add species to the lists; the processing of administrative petition findings to add species to the lists, delist species, or reclassify listed species (petitions filed under section 4 of the Act); and a limited number of proposed or final rules to delist or reclassify species. Third priority (Tier 3) is processing proposed or final rules designating critical habitat. The processing of this final rule is a Tier 2 action. We have updated this rule to reflect any changes in information concerning distribution, status, and threats since the publication of the proposed rule.

#### **Summary of Comments and Recommendations**

In the January 28, 1998, proposed rule and associated notifications, we requested all interested parties to submit factual reports or information that might contribute to the development of a final rule. We contacted and requested comments from all appropriate Federal and State agencies, County governments, scientific organizations, and other interested parties. We published newspaper notices requesting public comment on the proposed rule in *The*

*Salt Lake Tribune* and *the Deseret News* on February 10, 1998, and *the Daily Herald* on February 11, 1998.

In accordance with our policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we solicited the expert opinion of three appropriate and independent specialists regarding pertinent scientific or commercial data and assumptions relating to the supportive biological and ecological information for *Astragalus desereticus*. The purpose of this review is to ensure that listing decisions are based on scientifically sound data, assumptions, and analyses, including input of appropriate experts and specialists. One specialist responded in writing agreeing with our analysis and supporting the proposed action, while two others responded verbally agreeing with our analysis.

During the comment period we reviewed a total of three written comments. We did not receive any comments on the issues raised in our discussion of the biology or threats to the species. Two commenters, including the respondent peer reviewer, concurred with our proposal to list *Astragalus desereticus* as threatened. The third commenter stated that the Service should not list *A. desereticus* because it has no authority under the Act to list or regulate species that are not involved in interstate commerce.

We believe that the application of the Act to *Astragalus desereticus* does not exceed Congress's Commerce Clause authority under the U.S. Constitution for the reasons given in Judge Wald's opinion and Judge Henderson's concurring opinion in *National Association of Home Builders v. Babbitt*, 130 F.3d 1041 (D.C. Cir. 1997), *cert. denied*, 1185 S. Ct. 2340 (1998). That case involved a challenge to application of the Act's prohibitions to protect the listed Delhi Sands flower-loving fly. As with *A. desereticus*, the Delhi Sands flower-loving fly is endemic to only one state. Judge Wald held that application of the Act's prohibitions against taking of endangered species to this fly was a proper exercise of Commerce Clause power to regulate: (1) Use of channels of interstate commerce; and (2) activities substantially affecting interstate commerce because it prevented loss of biodiversity and destructive interstate competition. Judge Henderson upheld protection of the fly because doing so prevents harm to the development that is part of interstate commerce. See *Gibbs v. Babbitt*, 31 F.Supp.2d 531 (E.D.N.C. 1998).

#### **Summary of Factors Affecting the Species**

After a thorough review and consideration of all information available, we have determined that *Astragalus desereticus* should be classified as a threatened species. In making this determination we have followed the procedures set forth in section 4(a)(1) of the Act and regulations implementing the listing provisions of the Act (50 CFR part 424). We may determine a species to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Astragalus desereticus* Barneby (Deseret milk-vetch) are as follows:

##### *A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range*

*Astragalus desereticus* is known from one small population of about 5,000 reproducing individuals and several thousand immature plants on less than 120 ha (300 ac) (Franklin 1990, Stone 1992). This species is endemic to one unusual narrow geologic strata characterized by coarse, poorly sorted conglomerate. Any conversion or destruction of *A. desereticus* habitat has the potential to jeopardize the species' limited population. Urban development of the Wasatch Front metropolitan area is rapidly spreading into the surrounding agricultural lands, especially small communities in the drainages of the Provo, Spanish Fork, and Weber Rivers (Quality Growth Efficiency Tools Technical Committee 1997 (QGETTC)). The population growth of this metropolitan area is expected to double by the year 2020. In addition, conversion of agricultural land to urban use is expected to double in the same time period (QGETTC 1997). Highly accessible rural areas, such as Birdseye, may grow in population at an even more rapid rate. Since the species' rediscovery, one landowner has built a private residence within the species' occupied habitat. Prior to 1998, the town of Birdseye contained about 20 homes. Since the publication of the proposed rule, a 70-unit residential subdivision began construction adjacent to the south side of the species' population. The entire *A. desereticus* population is within 300 meters (m) (1,000 feet (ft)) of U.S. Highway 89. The nearest plants are within a few meters of the road. U.S. Highway 89 is currently a two-lane rural highway. With increasing human population in the general area of southern Utah County and northern Sanpete County, it

is likely that this road will be expanded to four lanes. Such a highway widening could destroy a significant portion of the species population (QGETTC 1997).

*Astragalus desereticus* is located on highly accessible public and private land that is currently used for cattle grazing and wildlife management (Franklin 1991, Stone 1992). The land managed by the Utah Division of Wildlife Resources is a wildlife management area that also is used for cattle grazing (Franklin 1991). Cattle are used by the Utah Division of Wildlife Resources (DWR) in spring to encourage plant growth for big game forage in the winter. This grazing occurs within the habitat of *A. desereticus* (Stone 1992). The cattle tend to concentrate primarily on the upslope areas where forage production is greater (Stone 1992). Erosion in these areas is exacerbated by cattle grazing and game trails. In addition to the effects of erosion, trampling threatens *A. desereticus* particularly at the southern end of the population (Franklin 1991). As cattle and wildlife graze the habitat of *A. desereticus*, the animals are likely to trample plants. Although mule deer numbers have stabilized in recent years, Rocky Mountain elk populations are increasing. Although currently DWR has no specific plans for the conservation of *A. desereticus*, they are interested in developing guidelines for the conservation of Deseret milkvetch to work in concert with their primary goal of enhancing big game winter range. The DWR is interested in acquiring property interests in additional winter range lands also occupied by *A. desereticus*.

#### B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overutilization is not known to be a threat to *Astragalus desereticus*.

#### C. Disease or Predation

In contrast to many species of *Astragalus*, *A. desereticus* appears to be palatable to cattle. The genus *Astragalus* has the largest number of species in the Intermountain west, many of which are poisonous to grazing animals. Three types of poisonous compounds are found within the genus. Some species within the genus concentrate the toxic element selenium in their tissues; these species are called selenophytes (Stone 1992). The fact that *A. desereticus* does not produce a "snake-like" odor typical of other "snakeweeds," as selenophytes are sometimes called, and the fact that no other selenophytes occur in the area, indicate that *A. desereticus* is not a selenophyte (Stone 1992). Other *Astragalus* species produce poisonous

alkaloids as metabolic byproducts. The known alkaloid producers as well as the selenium accumulators are not closely related to *A. desereticus*. The third type of poison found within *Astragalus* are various nitrotoxins. Ruminants in particular are highly susceptible to nitrotoxin poisoning. Some species closely related to *A. desereticus* contain nitrotoxins (Barneby 1989). While *A. desereticus* may not be preferred forage for cattle or native ungulates, it is palatable and may be inadvertently taken along with preferred forage in the area.

In surveys of habitat similar to that occupied by *Astragalus desereticus* in Utah County, our personnel observed that overgrazing by domestic ungulates has almost completely denuded the landscape (Service 1991). Similar grazing pressure is known from the current habitat of *A. desereticus*; therefore, the effects of grazing, particularly overgrazing, constitute a likely threat. This species is much less abundant in the more heavily grazed southern portion of its habitat (Franklin 1990, 1991), indicating that grazing may be a significant threat. Cattle grazing may be particularly harmful because it occurs during a critical period for *A. desereticus* reproduction (i.e., flowering) (Stone 1992).

There are no known insect parasites or disease organisms that significantly affect this species.

#### D. The Inadequacy of Existing Regulatory Mechanisms

*Astragalus desereticus* receives no protection or consideration under any Federal, State, or local law or regulation other than that provided by the Act.

#### E. Other Natural or Manmade Factors Affecting Its Continued Existence

By virtue of the limited number of individuals and range of the remaining population of *Astragalus desereticus*, this species is threatened with extinction from naturally occurring events. The probability that a natural event such as fire, drought, or disease will cause extinction is greater for species having a small population and highly restricted range (Stone 1992). Rare species in the genus *Astragalus* have exhibited low levels of genetic diversity when compared to other more widespread, closely related species (Stone 1992). Low genetic variability makes it difficult for a species to respond to changes in the environment thus making them more vulnerable to extinction.

The original locality description for *Astragalus desereticus* at Indianola is thought to be over-generalized and

perhaps this contributed to the species' presumed extinction (Welsh 1985, Franklin 1990). Indianola, Utah, and the species' current known population near Birdseye, Utah, are about 4.4 km (7 mi) apart. The specific geological characteristics of *A. desereticus* habitat are uncommon within the Moroni Formation, though the formation is exposed for a much larger area in southern Utah County and northern Sanpete County, Utah. Although it is thought that some additional populations of *A. desereticus* were present at or near Indianola as reported by Jones in 1893 and Tidestrom in 1909, there are no known populations existing in that location today. Other unknown factors may affect the current distribution and vitality of *A. desereticus* populations.

A potential threat to *Astragalus desereticus* is related to the populations of ungulates in the area and their effect on pollinators. Other species in the genus *Astragalus* suffer from low numbers of pollinators due to the indirect effect that ungulates can have on the pollinator's nest sites (Stone 1992). Bumblebees (*Bombus* spp.), which nest in abandoned rodent burrows, are likely the primary pollinators of *A. desereticus*. Land use practices that increase grazing pressure may cause burrows to collapse, destroying bumblebee nests (Stone 1992). Since bees have a low fecundity (low capability of producing offspring), their populations may not recover for many years, particularly if grazing by large ungulates is maintained. An absence of effective pollinators would probably reduce the fecundity of *A. desereticus*.

In preparing this final rule we have carefully reviewed the best scientific and commercial information available regarding the past, present, and future threats faced by *Astragalus desereticus*. Based on this evaluation, the preferred action is to list *A. desereticus* as threatened. Threatened status reflects the vulnerability of this species to factors that may negatively affect the species and its extremely limited habitat. While not in immediate danger of extinction, *A. desereticus* is likely to become an endangered species in the foreseeable future if present threats continue or increase. We have contacted the current land owners and although many are receptive in the near-term to providing for passive protection, having no immediate plans for development, in the long-term they continue to have expectations for the future use and development of their properties.

### Critical Habitat

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. Service regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) the species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species. We have determined that the designation of critical habitat for *A. desereticus* is not prudent due to the lack of benefit to the species.

Critical habitat receives consideration under section 7 of the Act with regard to actions carried out, authorized, or funded by a Federal agency (see "Available Conservation Measures" section). As such, designations of critical habitat may affect activities on Federal lands and may affect activities on non-Federal lands where such a Federal nexus exists. Under section 7 of the Act, Federal agencies are required to ensure that their actions do not jeopardize the continued existence of a listed species or result in destruction or adverse modification of critical habitat. However, both jeopardizing the continued existence of a species and adverse modification of critical habitat have similar standards and thus similar thresholds for violation of section 7 of the Act. In fact, biological opinions that conclude that a Federal agency action is likely to adversely modify critical habitat but not jeopardize the species for which the critical habitat has been designated are extremely rare. Also, the designation of critical habitat for the purpose of informing Federal agencies of the location of *A. desereticus* habitat is not necessary because we can inform Federal agencies through other means. For these reasons, the designation of critical habitat for *A. desereticus* would provide no additional benefit to the species beyond that conferred by listing, and, therefore, such designation is not prudent.

*Astragalus desereticus* has an extremely narrow distribution in a sandstone outcrop, totaling about 120 ha (300 ac) in one population. At the present time, no other site is known to be occupied or suitable for this plant. The private land owners at Birdseye are aware of the plant's presence and extremely limited habitat, as are the

DWR managers and others involved in the management of the area. Therefore, designation of critical habitat would provide no benefit with respect to notification. In addition, given the species' narrow distribution and precarious status, virtually any conceivable adverse affect to the species' habitat would very likely jeopardize its continued existence. Designation of critical habitat for *A. desereticus* would, therefore, provide no benefit to the species apart from the protection afforded by listing the plant as threatened.

Protection of the habitat of *A. desereticus* will be addressed through the section 4 recovery process and the section 7 consultation process. Although this plant occurs only on private and State land, it may be affected by projects with Federal connections, including potential Federal Highway Administration funding of road widening. We believe that activities involving a Federal action which may affect *A. desereticus* can be identified without designation of critical habitat, by providing Federal agencies with information on the location of occupied habitat and information on the kinds of activities which could affect the species. For the reasons discussed above, we find that the designation of critical habitat for *A. desereticus* is not prudent.

### Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups and individuals. The Act provides for possible land acquisition and cooperation with the State, and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not

likely to jeopardize the continued existence of such a species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us.

The single known population of *Astragalus desereticus* is on State and privately owned land. However, highway widening, which may adversely affect *A. desereticus*, due to the proximity of the plants to a major highway project, may in part be funded by the Federal Highway Administration and involve consultation under section 7 of the Act.

The Act and its implementing regulations set forth a series of general trade prohibitions and exceptions that apply to all threatened plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.71 for threatened plants, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in the course of a commercial activity, sell or offer for sale this species in interstate or foreign commerce, or remove and reduce the species to possession from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, damaging, or destruction of such plants in knowing violation of any State law or regulation, or in the course of a violation of State criminal trespass law. Section 4(d) of the Act allows for the provision of such protection to threatened species through regulation. This protection may apply to this species in the future if such regulations are promulgated. Seeds from cultivated specimens of threatened plants are exempt from these prohibitions provided that their containers are marked "Of Cultivated Origin." Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies.

The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened species under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation or survival of the species. For threatened plants, permits are also available for botanical and horticultural exhibition, educational purposes, or special reasons consistent with the Act's purposes. With respect to *Astragalus desereticus*, it is anticipated that few, if any, trade permits would be sought or issued since the species is not common in the wild

and is unknown in cultivation. Requests for copies of the regulations regarding listed species and inquiries about prohibitions and permits may be addressed to: Regional Director, U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225.

It is our policy, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable those activities that would or would not constitute a violation of section 9 of the Act if the species is listed. The intent of this policy is to increase public awareness of the effect of the listing on proposed and ongoing activities within a species' range. This species is not known to be located on areas under Federal jurisdiction. We believe the actions listed below would not result in a violation of section 9:

(1) Activities authorized, funded, or carried out by Federal agencies (e.g., grazing management, agricultural conversions, range management, rodent control, mineral development, road construction, human recreation, pesticide application, controlled burns) and construction/maintenance of projects (e.g., fences, power lines, pipelines, utility lines) when such activities are conducted according to all reasonable and prudent measures provided by the Service under section 7 of the Act;

(2) Casual, dispersed human activities on foot (e.g., bird watching, sightseeing, photography, and hiking).

The actions listed below may potentially result in a violation of section 9; however, possible violations are not limited to these actions alone:

(1) Unauthorized collecting of the species on Federal Lands;

(2) Application of herbicides in violation of label restrictions;

(3) Interstate or foreign commerce and import/export without previously obtaining an appropriate permit. Permits to conduct activities are available for scientific purposes, the enhancement of the propagation or survival, economic hardship, botanical or horticultural exhibition, educational purposes, or other activities consistent with the purposes and policy of the Act.

Questions regarding whether specific activities, such as changes in land use, would constitute a violation of section 9 should be directed to the Utah Ecological Services Field Office (see **ADDRESSES** section).

## National Environmental Policy Act

We have determined that Environmental Assessments and Environmental Impact Statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. A notice outlining the basis for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

## Required Determinations

This rule does not contain collections of information that require Office of Management and Budget approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An information collection related to the rule pertaining to permits for endangered and threatened species has OMB approval and is assigned clearance number 1018-0094. This rule does not alter that information collection requirement. For additional information concerning permits and associated requirements for threatened plants, see 50 CFR 17.72.

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Author: The primary author of this proposed rule is John L. England (see **ADDRESSES** section).

## List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

## Regulation Promulgation

Accordingly, amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

## PART 17—[AMENDED]

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

**Authority:** 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Pub. L. 99-625, 100 Stat. 3500, unless otherwise noted.

2. Amend section 17.12(h) by adding the following, in alphabetical order under "FLOWERING PLANTS," to the List of Endangered and Threatened Plants:

## § 17.12 Endangered and threatened plants.

\* \* \* \* \*

(h) \* \* \*

Species			Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*		*
<i>Astragalus desereticus</i> .....	Deseret milk-vetch .....	U.S.A. (UT) .....	T	668	NA	NA	
*	*	*	*	*		*	

Dated: September 30, 1999.

**Jamie Rappaport Clark,**

*Director, Fish and Wildlife Service.*

[FR Doc. 99-27187 Filed 10-19-99; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

RIN 1018-AE 86

#### Endangered and Threatened Wildlife and Plants; Final Rule To List the Devils River Minnow as Threatened

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, determine the Devils River minnow (*Dionda diaboli*) to be a threatened species under the authority of the Endangered Species Act of 1973, as amended (Act). The Devils River minnow is a small fish with a known distribution limited to three locations in Val Verde and Kinney counties, Texas, and one drainage in Coahuila, Mexico. The species' range is significantly reduced and fragmented due to habitat loss from dam construction, spring dewatering, and other stream modifications. The numbers of Devils River minnows collected during fish surveys over the past 25 years have declined; once one of the most abundant fish in the Devils River, the minnow has now become one of the least abundant. The species' decline in abundance in the Devils River may be attributed to the effects of both habitat modification and possibly predation by smallmouth bass (*Micropterus dolomieu*), an introduced game fish.

We originally proposed to list the Devils River minnow as endangered. However, since publication of the proposed rule, a Conservation Agreement (Agreement) for the species has been signed and specific milestones for conservation actions have been agreed to by us, the Texas Parks and Wildlife Department (TPWD), and the City of Del Rio. We determine that the

actions already accomplished under this Agreement, have reduced the imminence of the threats to the species sufficiently to justify a threatened designation. This action will implement Federal protection provided by the Act for the Devils River minnow. We determine that designation of critical habitat for the Devils River minnow is not prudent.

**EFFECTIVE DATES:** The effective date of this rule is November 19, 1999.

**ADDRESSES:** The complete file for this rule is available for inspection, by appointment, during normal business hours at the Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas, 78758.

**FOR FURTHER INFORMATION CONTACT:** Nathan Allan, Fish and Wildlife Biologist, at the above address, telephone 512/490-0057, or facsimile 512/490-0974.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Devils River minnow (*Dionda diaboli* Hubbs and Brown) is classified in the Cyprinidae (minnow) family. It was first collected from Las Moras Creek, near Brackettville, Texas, on April 14, 1951. The species was described by Hubbs and Brown (1956) from specimens collected in the Devils River at Baker's Crossing (southern-most bridge crossing of State Highway 163) in 1951. The species occurs with similar minnows, such as the closely related manantial roundnose minnow (*Dionda argentosa*) and is also related to the more common roundnose minnow (*Dionda episcopa*). Devils River minnow is recognized as a distinct species by the American Fisheries Society (Robins *et al.* 1991) based on morphological characteristics (Hubbs and Brown 1956), genetic markers (Mayden *et al.* 1992), and chromosome differences (Gold *et al.* 1992).

The Devils River minnow is a small fish, with adults reaching sizes of 25–53 millimeters (mm) (1.0–2.1 inches (in.)) standard length. The fish has a wedge-shaped caudal (near the tail) spot and pronounced lateral stripe with double dashes extending through the eye to the snout but not reaching the lower lip.

The species has a narrow head with prominent dark markings on scale pockets above the lateral line that produce a cross-hatched appearance when viewed from the top (Hubbs and Brown 1956).

Little information is available on life history characteristics, feeding patterns, or reproductive behaviors of this species. However, based on their extended intestinal tract, species of the genus *Dionda* are considered to feed primarily on algae. Since *Dionda episcopa*, a closely related species, are broadcast spawners with nonadhesive eggs that sink to the substrate (Johnston and Page 1992), we believe Devils River minnows are as well.

General habitat associations for Devils River minnow have been described as channels of fast-flowing, spring-fed waters over gravel substrates (Harrell 1978). Although the species is closely associated with spring systems, it most often occurs where spring flow enters a stream, rather than in the spring outflow itself (Hubbs and Garrett 1990). The species is adapted to the hydrologic variations inherent in desert river systems (Harrell 1978), which are characterized by extended droughts and extreme flash floods (USGS 1989).

The Devils River minnow is part of a unique fish fauna in west Texas streams where a mixture of fishes occur, including Mexican peripherals, local endemics, and widespread North American fishes (Hubbs 1957). About half of the native fishes of the Chihuahuan Desert of Mexico and Texas are considered by Hubbs as threatened (1990) and at least four species have been documented to be extinct (Miller *et al.* 1989), primarily due to habitat destruction and introduced species.

The Devils River minnow is native to tributary streams of the Rio Grande in Val Verde and Kinney counties, Texas, and Coahuila, Mexico. The known historical range of the species is based on collections from the 1950's and 1970's and includes the Devils River from Beaver Lake downstream to near its confluence with the Rio Grande; San Felipe Creek from the springs in the headwaters to springs in Del Rio; Sycamore Creek; Las Moras Creek near

Brackettville; Rio San Carlos, Mexico; and the Rio Salado Drainage, Mexico (Brown 1955; Hubbs and Brown 1956; Robinson 1959; Harrell 1978; Smith and Miller 1986; Garrett *et al.*, 1992).

Despite numerous collection efforts, the species has never been reported from the mainstem Rio Grande, the Rio Conchos drainage, or tributary streams other than those listed above. The range of the species prior to 1951 is unknown.

A comprehensive assessment of the distribution of Devils River minnow in Texas was described by Garrett *et al.* (1992). This study documented the presence of the species in 1989 at two sites on the Devils River (Baker's Crossing and Dolan Springs), two sites on San Felipe Creek, and one site on Sycamore Creek. None were collected in samples from Las Moras Creek.

Garrett *et al.* (1992) found that Devils River minnow was very rare throughout its range in 1989 compared to past collections. At 24 sampling locations within the historical range, a total of only 7 individuals were collected from 5 sites. In addition to declines in the Devils River minnow populations, Garrett *et al.* (1992) also observed a general shift in community structure toward fishes that tend to occupy quiet water or pool habitat, conditions that are often limited in flowing spring runs. The authors hypothesized that this shift was the result of reduced stream flows from drought, exacerbated by human modification of stream habitats, especially in Sycamore and Las Moras creeks.

The most recent information from collections in 1997 and 1998 confirm the existence of Devils River minnow in only three locations in Texas—two sites in small streams tributary to the Devils River (Phillips Creek and Dolan Creek) and one site in San Felipe Creek in Del Rio.

We are unaware of any published information on the status of the Devils River minnow in Mexico. A review of museum records indicates that the species may now occur in only one locality in Mexico. Populations there appear to be very depressed (S. Contreras-Balderas, University of Nuevo Leon, *in litt.* 1997) and face significant threats from industrial and agricultural development (Contreras and Lozano 1994).

The region of Texas where the Devils River minnow occurs is semi-arid, receiving an average of about 46 centimeters (cm) (18 in.) of rainfall annually. Spring-fed streams of west Texas flow southerly through rocky, limestone soils and shrubby vegetation characteristic of the more arid western reaches of the Hill Country. The aquifer

that sustains spring flows within the range of the Devils River minnow is the Edwards-Trinity (Plateau) Aquifer. This major aquifer produces the largest number of springs in Texas (Brune 1975). The contributing and recharge area for springs on the Devils River and San Felipe Creek is suspected to include a large area as far north as Sheffield in Pecos County and Eldorado in Schleicher County, although the subsurface hydrogeomorphology (underground water characteristics) of the region is not well-defined (Brune 1981). The flow from springs fluctuates considerably, depending on the amount of rainfall, recharge, and water in storage in the aquifer. Conservation of the quality and quantity of this groundwater supply is essential for the continued existence of the Devils River minnow.

Areas where the Devils River minnow occurs are mostly in private ownership. Exceptions include the Devils River State Natural Area located north of Dolan Falls and managed by the TPWD (Baxter 1993), and land adjoining portions of San Felipe Creek owned by the City of Del Rio (population of about 38,000). One important private holding is the Dolan Falls Preserve, in the middle portion of the Devils River, owned by The Nature Conservancy (Baxter 1993). Primary land uses within the watersheds supporting Devils River minnow are cattle, sheep, and goat ranching. Generally, these areas are very remote with little human development beyond that necessary to support ranching operations.

The Devils River minnow is currently listed as a threatened species by the State of Texas, the Texas Organization for Endangered Species (Hubbs *et al.* 1991), and the Endangered Species Committee of the American Fisheries Society (Williams *et al.* 1989). The Devils River minnow is listed as an endangered species in Mexico (NOM-ECOL-059).

The Agreement for Devils River minnow was signed by the Service, the TPWD (in cooperation with local landowners), and the City of Del Rio on September 2, 1998, to expedite conservation measures needed to ensure the continued existence of the species. Preliminary drafts of the Agreement were made available to local landowners for comment and a draft version was also distributed at a public hearing on the proposal to list the species. The Agreement includes a Conservation Strategy (Strategy) to describe the specific procedures required for conservation of the Devils River minnow. We carefully considered the implementation to date of the

conservation actions as described in the Strategy and the effects of that implementation on removing threats to the species when making the final listing determination for the Devils River minnow. Following is a discussion of the conservation actions and implementation that have occurred to date.

The ten conservation actions that are included in the Strategy and their implementation status are:

(1) Determine the current status of the Devils River minnow and monitor changes. This action was initiated in November 1997, (prior to signing the Agreement) with sampling in the mainstem Devils River and San Felipe Creek in Del Rio and continued with collections from Phillips Creek and Dolan Creek in May, 1998.

(2) Maintain genetically representative, captive populations of Devils River minnow at two fish hatchery facilities for reintroduction, and as insurance against extinction. This action has been initiated by the TPWD by holding a small number of individuals of Devils River minnow at a hatchery since November 1997. Those individuals produced an unassisted reproductive effort in March 1999, in an artificial stream, indicating that captive propagation is likely readily accomplished. We agreed to assist in this action by providing an additional location to develop captive propagation techniques for the species. We have secured funding for our San Marcos National Fish Hatchery and Technology Center to initiate this action in the very near future.

(3) Reintroduce Devils River minnows, reared in captive populations, in order to reestablish populations in nature. This action has not yet been implemented and depends on a number of other actions being completed before reintroductions can be initiated.

(4) Continue and enhance protection of the San Felipe Creek watershed. This action by the City of Del Rio to protect San Felipe Creek has not yet been implemented. The City has committed to a concept of conservation of the natural environment in any future development plans within the riparian zone of the creek (Beth Eby, City Manager, City of Del Rio, *in litt.* 1997). This action will be an ongoing effort by the City for protection of this population of Devils River minnow.

(5) Provide technical assistance to landowners on riparian protection and management. Not yet initiated.

(6) Review live bait harvest and selling practices in the Devils River area to develop methods and take appropriate actions (for example,

regulation, education) to prevent the further establishment of exotic aquatic species within the historical range of Devils River minnow. Not yet initiated.

(7) Document the abundance and ranges of exotic fish in the Devils River, and San Felipe, Las Moras, and Sycamore creeks. Not yet initiated.

(8) Obtain and analyze changes in flow data for the Devils River, and San Felipe, Las Moras, and Sycamore creeks. Not yet initiated.

(9) With progeny of the captive population, use a simulated environment to determine ecological and life history requirements of the Devils River minnow. The TPWD has initiated this action through the purchase and construction of the facilities necessary to do experiments on the ecology of the species. Preliminary experiments have been initiated.

(10) Determine predator/prey interactions between smallmouth bass and the Devils River minnow through field studies. This action will depend in part on the completion of a current study by Texas A&M University and implementation of laboratory experiments discussed in action number 9, above.

In February 1999, we requested confirmation from the TPWD and the City of Del Rio of their commitment to implementation of the Agreement, and clarified some specific milestones for accomplishing the goals of the Agreement. The TPWD and the City concurred in writing to implement key components of the Agreement within the next 2 years. The milestones agreed to by the three parties include:

(1) Have healthy, genetically representative captive stocks of Devils River minnow in at least two facilities. Each facility should maintain two separate stocks, one from the Devils River and one from San Felipe Creek.

(2) Conduct the first annual population monitoring for the Devils River minnow throughout its historical range in the U.S.

(3) Conduct the first annual monitoring for the Devils River minnow throughout its historical range and potential habitats in Mexico.

(4) Conduct the second annual population monitoring for the Devils River minnow throughout its historical range in the U.S.

(5) Improve the status of the Devils River minnow in San Felipe Creek at Del Rio and restore Devils River minnow populations in the headwater springs area. This will be indicated by maintaining stable population sizes of Devils River minnow at Del Rio and restoring population sizes at least equal to those historically in the headwater

springs. In addition, implementation of conservation measures in San Felipe Creek in Del Rio (such as a finalized policy by the City of Del Rio for preservation of the San Felipe Creek watershed, development of a San Felipe Creek floodplain restoration plan, completion of a water conservation plan, and completion of a management plan for the golf course) will be completed to reduce threats to the species there.

(6) Improve the status of the Devils River minnow in the Devils River. This will be accomplished by establishing additional locations of Devils River minnow, with population sizes at least equal to historical levels (such as similar to those found by H.L. Harrell in the 1970's). This will include further threat assessment and addressing potential limiting factors in this system, particularly the effects of smallmouth bass and changes in stream flows.

We concur with many of the public comments that supported this cooperative approach. This listing does not preclude continuation of cooperative efforts between parties to the Agreement or continuing efforts to implement the Conservation Strategy. As stated in the introduction of the Agreement, we believe that full implementation of the Strategy may ultimately reduce the threats to the Devils River minnow and allow a future review of the species' status. This could result in a future delisting if threats are removed and the status of the species significantly improves such that recovery has occurred.

#### **Previous Federal Action**

On August 15, 1978, we published a proposed rule (43 FR 36117) to list the Devils River minnow as a threatened species and to designate its critical habitat. On March 6, 1979, we published a notice (44 FR 12382) to withdraw the critical habitat portion of the proposal to meet the new critical habitat requirements set forth in the Endangered Species Act Amendments of 1978 (Public Law 95-632, 92 Stat. 3751). We repropounded the designation of critical habitat for the Devils River minnow on May 16, 1980 (45 FR 32348). A notice of public hearing was published on July 9, 1980 (45 FR 46141), and the public hearing was held on July 23, 1980, in Del Rio, Texas. The 1978 amendments to the Act also required that all proposals over two years old be withdrawn. We withdrew the listing and critical habitat proposals on September 30, 1980 (45 FR 64853), because the 2-year time limit on the proposed listing had expired.

We included the Devils River minnow as a category 2 candidate species in notices of review published December 30, 1982 (47 FR 38454), September 18, 1985 (50 FR 37958), and January 6, 1989 (54 FR 554). Category 2 taxa were those that we believed may be eligible for threatened or endangered status, but for which the available biological information in our possession was insufficient to support listing the species. However, new information obtained in 1989 (and later published as Garrett *et al.* 1992) provided a basis for including the Devils River minnow as a category 1 candidate in notices of review published November 21, 1991 (56 FR 58804), and November 15, 1994 (59 FR 58982). Category 1 taxa were those for which we had substantial biological information on hand to support proposing to list the species as threatened or endangered.

As announced in a notice published in the February 28, 1996, **Federal Register** (61 FR 7596), the designation of multiple categories of candidates was discontinued, and only species for which we have sufficient information to support listing are now recognized as candidates. The Devils River minnow remained a candidate species in notices of review published February 28, 1996 (61 FR 7596), and September 19, 1997 (62 FR 49398).

On March 27, 1998, we published a proposed rule to list the Devils River minnow as endangered and invited public comment (63 FR 14885). On May 14, 1998, we published a notice of public hearing on the proposal (63 FR 26764), and a public hearing was subsequently held in Del Rio, Texas, on May 28, 1998. On October 13, 1998, we published a notice reopening the comment period on the proposed rule for an additional 30 days and announcing the availability of new information and the Conservation Agreement (63 FR 54660).

The processing of this final rule conforms with our current listing priority guidance published in the **Federal Register** on May 8, 1998 (63 FR 25503). The guidance calls for giving highest priority to handling emergency situations (Tier 1) and second highest priority to resolving the listing status of outstanding proposed listings, resolving the conservation status of candidate species, processing petitions, and delisting or reclassifications (Tier 2). The guidance assigns the lowest priority (Tier 3) to processing proposed or final designations of critical habitat. Processing of this final rule is a Tier 2 action.



## Summary of Comments and Recommendations

In the March 27, 1998, proposed rule (63 FR 14885), the May 14, 1998, public hearing notice (63 FR 26764), and the October 13, 1998, notice reopening the comment period (63 FR 54660), we requested all interested parties to submit factual reports or information that might contribute to the development of a final rule. The original public comment period extended 120 days from the date of the proposal and closed on July 27, 1998. The comment period was reopened for an additional 30 days on October 13, 1998, and closed on November 12, 1998. The second comment period was reopened to accept comments on the proposal after the original comment period closed. Updated information on the distribution and abundance of the species was provided by the TPWD (G. Graham, TPWD, *in litt.* 1998). In addition, a Conservation Agreement for the Devils River minnow among us, the TPWD, and the City of Del Rio was signed on September 2, 1998.

We contacted numerous Federal and State agencies, county and municipal governments, scientific organizations, and private individuals to request comments on the proposal. Newspaper notices inviting public comment and announcing the public hearing were published between May 3 and May 12, 1998, in the *Sanderson Times*, *Del Rio News Herald*, *Odessa American*, *San Angelo Standard Times*, *Midland Reporter-Telegram*, *Devils River News*, and the *Ozona Stockman*.

The public hearing was held in Del Rio on May 28, 1998. About 50 people attended, and 18 made oral statements. We also received 13 written comments from the public and agency officials during both comment periods. Four of the oral comments at the public hearing were the same or similar to written comments submitted by the same parties. One person submitted two comment letters. Therefore, comments were received from 26 separate commenters on the proposal.

The following summary addresses the written and oral comments received. These comments comprise a range of issues regarding the proposal. Because multiple respondents offered similar comments in some cases, those comments were combined. Of those commenters stating a position, 11 clearly indicated opposition to the listing and another 8 implied that they were opposed. Seven commenters did not clearly state a position. Ten commenters expressed support for the

Conservation Agreement. The comments and our responses are as follows:

*Comment 1:* There is a need for more information on the Devils River minnow before a decision is made. The distribution and abundance of the fish is likely larger than reported in the proposal, both in the U.S. and Mexico.

*Service Response:* We agree that more can be learned about the Devils River minnow and its conservation with additional research. The Conservation Agreement has additional research and monitoring as key components for benefitting the species (see the "Background" section of this final rule). However, we must base the listing decision on the best information available at this time. With the current data, we conclude that the fish has declined over a significant portion of its range. Therefore, based on the best available information, threatened status for the Devils River minnow is warranted.

*Comment 2:* Numerous commenters requested that we accept the Conservation Agreement among the Fish and Wildlife Service, TPWD, and the City of Del Rio in lieu of listing the minnow. Many believed this is a better approach to management of the Devils River minnow.

*Service Response:* We agree that cooperative, voluntary efforts to conserve this species that remove or reduce threats that preclude the need to list would be preferable to Federal listing. However, full implementation of the conservation strategy activities that the agreement calls for has not occurred. We signed the Conservation Agreement so that conservation efforts could be quickly put in place to reduce the risks to the species' survival. We have considered the extent to which the conservation actions outlined in the Conservation Agreement have been implemented and are likely to reduce threats to the species, particularly in the near-term, in making this listing determination. We strongly support the efforts of State and local agencies taking active roles in the conservation of the Devils River minnow, and we believe the Agreement and actions outlined in it have the potential to benefit the species. The actions already accomplished in the Conservation Agreement, as well as the agreed-upon schedule for implementing the remaining actions, were considered in the decision to list as threatened. We believe that the conservation agreement is an important conservation tool. Even though full implementation has not occurred and we determined that threats to the species still exist such that listing is still warranted, the Conservation

Agreement will be useful in facilitating and expediting the recovery of the Devils River minnow.

*Comment 3:* Some commenters requested the listing decision be delayed to allow the Conservation Agreement time to be implemented.

*Service Response:* We are required by section 4 of the Act to publish a final decision within one year of a proposed rule. We took into account those actions of the Conservation Agreement that have been implemented to date and the benefits expected from actions that will be implemented in the near future. We determined that, within the statutory time frames mandated by the Act, listing the Devils River minnow as threatened at this time is the best course of action.

*Comment 4:* Several commenters stated a strong desire to not incur additional Federal regulations over land and water use that would limit private property rights.

*Service Response:* We do not foresee substantial impacts on private property rights through the Devils River minnow. In the "Available Conservation Measures" section of this final rule, we have outlined some private activities that likely will and likely will not result in take of the species under the prohibitions of section 9 of the Act. We are interested in working with landowners to develop cooperative solutions to species conservation that avoid or minimize the need for regulatory burdens on landowners.

*Comment 5:* Local and state governmental agencies could manage the Devils River minnow better than the Federal government.

*Service Response:* Listing the species by the Federal government does not preclude State and local management of the species. On the contrary, we encourage State and local involvement in recovery of endangered species. We believe that local actions are crucial to long-term conservation of this species. We believe a cooperative approach by all parties will provide an even greater benefit to the species, and we offer any support where possible and needed.

*Comment 6:* No significant groundwater pumping has occurred in the watershed since the 1960's.

*Service Response:* We took this comment into consideration in this final rule (see discussion in the "Summary of Factors Affecting the Species" section) and have modified the discussion of this topic. Because of the lack of information on groundwater withdrawals, we do not have substantial information showing the level of pumping in and around the Devils River watershed. This prevents any correlation of streamflow with groundwater withdrawals. However,

sources such as Dietz (1955) and Brune (1981) claim that groundwater withdrawals have affected stream flows. We believe there is a potential that groundwater pumping could adversely affect habitat of the Devils River minnow.

*Comment 7:* There have not been any changes in stream flows in the Devils River, and no data exist that suggest otherwise. In addition, there has never been permanent stream flow in the reach from Beaver Lake to Pecan Springs.

*Service Response:* The information used in evaluating historical stream flow on the Devils River is from gage records collected by the International Boundary and Water Commission at the gage near Del Rio (1900–1957), the gage at Pafford Crossing (1960–1997), and the gage near Juno (1925–1973). We did not locate any specific studies or analysis of hydrology on the Devils River.

We reevaluated all existing and new information concerning the presence of permanent flow between Pecan Springs and Beaver Lake on the Devils River. The “Summary of Factors Affecting the Species” section of this rule reflects the available information. One task included in the Conservation Agreement is an analysis of the hydrology of the Devils River and other streams supporting Devils River minnow to determine if stream flows have declined over time.

*Comment 8:* No changes in grazing practices have occurred in recent times. Instead, the land is actually in better condition today than in previous times and the only changes have been an increase in the amount of cedar and mesquite.

*Service Response:* We took this comment into consideration in this final rule (see discussion in the “Summary of Factors Affecting the Species” section) and have modified the discussion of this topic. The proposed rule did not state that land use practices, such as grazing, were known to be a major threat to the Devils River minnow. Instead we cited Brune’s (1981) statement that some land use practices, such as overgrazing, that result in the loss of native rangeland grasses on the watershed, could lead to increased runoff and decreased groundwater recharge.

We do not have specific evidence that land use practices are a significant reason for the current decline in the species’ distribution and abundance. However, Brune (1981) stated that if upland areas are poorly managed, one long-term effect is an increased rate of rainfall runoff and decreased rates of recharge to the groundwater.

*Comment 9:* One commenter stated that there have never been any Devils River minnows collected from Beaver Lake or anywhere upstream of Pecan Springs.

*Service Response:* In September 1973, and March 1974, H. Harrell collected Devils River minnow in Beaver Lake. Voucher specimens are deposited in the Strecker Museum, Baylor University. The 1973 sample contains 14 specimens and the 1974 sample contains 13 specimens of Devils River minnow.

*Comment 10:* The actual abundance of Devils River minnow is higher than reported in the proposed rule. The recent collections of Devils River minnow from Phillips Creek and Dolan Creek show they are plentiful.

*Service Response:* The new information on the presence of the Devils River minnow in Phillips and Dolan creeks is included in this final rule. The number of fish in Phillips Creek taken in May 1998, indicated a good population at this site at the time the collections were made. The collections at Dolan Creek are important because the only other collection of the species from this site was one specimen in 1989 (Garrett *et al.* 1992). The two locations in the Devils River drainage are less than 20 river-km (13 river-mi) apart and are not sufficient to alleviate the concern for the status of the species in the Devils River or other portions of its range. The most recent information can only confirm three locations of the species throughout its historical range in the U.S. (these two in the Devils River and one at Del Rio in San Felipe Creek). Although population numbers are important, the determination to list a species is based on the five factors outlined in section 4 of the Act and summarized in this final rule under the “Summary of Factors Affecting the Species” section.

*Comment 11:* Devils River minnows are rare in the Devils River because of the introduction of smallmouth bass by TPWD.

*Service Response:* We agree that predation by smallmouth bass could be a significant factor in the decline of Devils River minnow in the Devils River. Identification of the significance of this threat is one of the actions included in the Conservation Agreement (Conservation Action #8).

*Comment 12:* It is illogical to expect the Devils River minnow population in the Devils River to be reestablished to 1950-levels under today’s vastly changed circumstances, such as Amistad Dam.

*Service Response:* Destruction of the species’ habitat, such as what resulted from Amistad Dam, is one of the five

factors we are required to consider (See the “Summary of Factors Affecting the Species” section below) when deciding if a species is threatened or endangered. However, when planning recovery, we do not expect to restore populations of Devils River minnow to historical locations because some habitat changes are not reversible. We do believe the Devils River minnow can be protected from extinction through conservation of the remaining ecosystems upon which the species depends. The past habitat destruction only serves to heighten the need for protection and enhancement of suitable habitats remaining for the Devils River minnow.

*Comment 13:* The Natural Resources Conservation Service (NRCS) requested we remove their agency from the list of Federal agencies that may have actions that require consultation under section 7 of the Act. The NRCS indicated that none of their programs adversely affected the minnow, but served to benefit the minnow by improving habitat.

*Service Response:* We support the NRCS in assisting landowners with ranching practices that may benefit Devils River minnow habitat. However, we left the NRCS as a potential agency for consultations because the Act mandates that any Federal action that may affect a listed species, even if that effect is beneficial, requires consultation with us under section 7 of the Act. We included language in this final rule (see Available Conservation Measures, below) to explain the requirements of Federal agencies under section 7(a)(1) of the Act.

*Comment 14:* The proposed rule does not indicate the Devils River minnow is bred or hunted for commercial purposes, or that it moves in interstate commerce. Therefore, the Service lacks authority under the Act pursuant to the Commerce Clause of Article 1, section 8 of the United States Constitution to regulate the Devils River minnow.

*Service Response:* A recent decision in the United States Court of Appeals for the District of Columbia Circuit (*National Association of Homebuilders v. Babbitt*, 130 F. 3d 1041, D.C. Cir. 1997) makes it clear in its application of the test used in the United States Supreme Court case, *United States v. Lopez*, 514 U.S. 549 (1995), that regulation of species limited to one State under the Act is within Congress’ commerce clause power. On June 22, 1998, the Supreme Court declined to accept an appeal of this case (118 S. Ct. 2340 1998). Therefore, our application of the Act to Devils River minnow, a fish endemic to only two counties in the State of Texas, is constitutional. We

have authority under the Act to list the Devils River minnow as threatened and direct its conservation and eventual recovery.

In addition to the reasons supporting the constitutionality of the Act itself that were discussed in *National Association of Homebuilders v. Babbitt*, the past, current, and potentially future use of Devils River minnow habitat for agriculture and livestock production, residential development and roads and highways are activities that affect interstate commerce. The specimens of this species in museums around the country directly traveled via the channels of interstate commerce, as well as the scientists and others who have traveled interstate to study or observe the species. Finally, international commerce between the U.S. and Mexico, where the species also occurs, may impact Devils River minnow habitat and is also under the authority of Federal regulation.

*Comment 15:* The Service is intentionally making untrue, nonscientific statements to serve a political agenda to list the Devils River minnow.

*Service Response:* In both the proposed rule and this final rule we conducted an objective evaluation of the scientific evidence available to reach a decision on whether the Devils River minnow warrants listing under the Act. Where additional information was submitted to us, we have considered that new information as well. The information upon which this decision is based has been peer reviewed by independent experts outside the Service, as required by our 1994 Peer Review Policy (see discussion below).

#### Peer Review

Service policy (59 FR 34270; July 1, 1994) requires that we solicit review of listing actions from a minimum of three independent experts. We sent copies of the proposed rule, supporting primary literature, and other information to five independent specialists who have extensive knowledge in the biology and ecology of Devils River minnow or other native fishes. Four of these specialists are currently employed at universities conducting research on fishes and one reviewer is a retired fishery biologist from a state agency, currently serving as Executive Secretary of a scientific society specializing in native fishes of the southwestern U.S. Four peer reviewers responded to our request.

All four reviewers indicated the proposal was consistent with the information available in the scientific literature. Three of the reviewers indicated that the proposal to list the

Devils River minnow was clearly supported by the scientific literature, emphasizing that the factors cited in the proposal were real threats to the continued existence of the species. One reviewer pointed out the lack of intensive surveys to determine the exact status of the species as a weakness in the available information. However, we believe that sufficient surveys have been conducted to demonstrate a significant range reduction for the Devils River minnow.

#### Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, we determine that the Devils River minnow should be classified as a threatened species. Procedures found at section 4(a)(1) of the Act (16 U.S.C. 1531 *et seq.*) and regulations implementing the listing provisions of the Act (50 CFR part 424) were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the Devils River minnow (*Dionda diaboli*) are as follows:

##### A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

###### Devils River

The Devils River is the largest segment of the historical documented range of the Devils River minnow. The Devils River from Beaver Lake to its confluence with the Rio Grande is about 127 river-km (79 river-mi) long. At least one-quarter of the total length of the Devils River, from Big Satan Canyon to the Rio Grande, has been permanently lost as potential habitat due to inundation behind Amistad Dam.

One of the most significant losses of Devils River minnow habitat occurred in the lower portion of the Devils River with the impoundment of Amistad Reservoir in 1968. The river downstream of Big Satan Canyon is often inundated by Amistad Reservoir and the river can be affected farther upstream when the reservoir level is high. Backwaters from Amistad Dam have inundated the natural stream habitats, transforming the area from a river to a lake environment. The area is no longer suitable for most native fishes, including Devils River minnow.

Before construction of Amistad Dam, two smaller dams (Devils Lake and Wall Lake) were built in about the 1920's in the lower portion of the stream. However, Devils River minnows were collected in 1953 and 1954 in the spring

run habitat that remained. Amistad Reservoir, however, inundated these springs, eliminating the natural environment and suitable habitat for native fish. Also, the construction of the dam created a physical barrier to fish movement that permanently separated the Devils River population of the species from others, such as the population in San Felipe Creek.

Habitat for the species may be affected by inconsistent spring flows in the upstream portion of the Devils River, especially between Pecan Springs and Beaver Lake (about 26 km, 16 mi). The only discharge records in this portion of the river are from a gage near Juno, located downstream of Pecan Springs (International Boundary and Water Commission, unpublished data, *in litt.*, 1997) that was discontinued in 1973 and has no records from 1949 to 1963. The available data from this gage show an average base flow (based on the monthly median discharge) in the range of about 1,982 to 2,832 liters per second (lps) (70 to 100 cubic feet per second (cfs)) from 1925 to 1949 and a range of about 991 to 1982 lps (35 to 70 cfs) from 1963 to 1973.

We based our assessment of the uppermost portion of the river on published observational data. One of the earliest descriptions of the Devils River is from Taylor (1904) who stated the river "rises" at Pecan Springs. It is unclear from this account whether there was any flow upstream of this spring system. However, Brune (1975 and 1981) clearly states that the river once flowed from Beaver Lake, as did other springs downstream from Beaver Lake such as Juno, Headwater, Stein, and San Pedro springs, but has dried in recent times. Brune (1975 and 1981) supports this by—(1) referencing an observation from 1916 that described the Beaver Lake area as a beautiful stream; (2) providing flow data from Beaver Lake in 1925 at 45 lps (1.59 cfs) and in 1939 at 0.38 lps (0.01 cfs); and, (3) recording no surface flow from these springs in 1971 and 1976.

Harrell (1978) collected Devils River minnow from the Beaver Lake area in 1973 and 1974 (specimens in Strecker Museum, Baylor University). This indicates that there was sufficient surface flow in the area during those years to support populations of the fish. However, Harrell (1978) states that during the study period in 1974–75, Pecan Springs was the uppermost flowing surface water connected to the river. Harrell (1978) further states that the upper portion of the Devils River (Beaver Lake to Baker's Crossing) has intermittent flow characterized by

numerous rapids (citing Belisle and Josselet 1975).

The available information indicates that the flow of the Devils River upstream of Pecan Springs is intermittent and is connected to downstream surface flows only during wetter climatic conditions. The Devils River minnow has been documented in these areas in the past and, therefore, this reach is considered potential habitat for the species. This habitat is likely also naturally intermittent and may not have been continuously occupied by the fish during recent time.

Observations in 1954 and 1955 suggested a significant increase in irrigation farming from groundwater wells in the area of Juno and the headwaters of the Devils River (Dietz 1955). The result reported by Dietz (1955) was the lowering of the groundwater to a level causing the Devils River to cease flowing for a number of miles below Baker's Crossing. The upper portion of the Devils River is likely the most susceptible to declines in groundwater levels.

Brune (1981) states that agricultural land use practices (specifically the decline of grasses from livestock grazing) both within and north of the watershed of the Devils River may affect aquifer levels and account for a lack of permanent flows from the northernmost springs. Brune (1981) explains that the natural layer of organic mulch that formerly functioned as a topsoil capable of absorbing rainfall has been lost and replaced with barer soils that enhance runoff and limit recharge.

Another cumulative factor may be the expansion of Ashe juniper (*Juniperus ashei*) and Redberry juniper (*Juniperus pinchotti*), both commonly referred to as cedar. These two species have become abundant on the rangeland watersheds of the Devils River due to a number of natural and human factors (Smiens *et al.* 1997). The overabundance of juniper has been cited as a factor that could affect rangeland hydrology (Thurrow and Hester 1997). However, definitive data are not available to show that removal of juniper will produce increased groundwater levels in Texas. Studies of juniper removal in other states have not resulted in significant yields to groundwater or stream flows (Thurrow and Hester 1997).

Any decline of permanent discharge from springs is a significant threat to Devils River minnow in the Devils River. This threat can be the result of drought and/or human activities that withdraw groundwater or significantly reduce recharge. The downstream portion of the Devils River below Baker's Crossing continues to flow

naturally and has been referred to as one of the most pristine rivers in Texas. Because of groundwater reservoirs that support the remaining spring systems, the river maintains a substantial perennial flow in the range of 200 to 400 cfs at the inflow to Amistad Reservoir (unpublished data, International Boundary and Water Commission, *in litt.* 1997).

When spring flows become seasonally intermittent, fish populations are unable to use the stream to fulfill their life history requirements. Declines in base flow of streams also affect fish populations by reducing the total available habitat and thereby intensifying competitive and predatory interactions. For Devils River minnow, decreased stream flows could lead to a population decline due to exclusion from preferred habitats and increased mortality from predation.

The eighth action listed in the Conservation Strategy of the Agreement requires the analysis of past changes in flows throughout the range of the Devils River minnow. These studies will determine the potential effects of flows on habitat for Devils River minnow.

Using relative abundance as an indicator, the Devils River minnow has decreased in abundance in the Devils River over time. The Devils River minnow was the fifth most abundant species of 18 species collected in 1953 at Baker's Crossing (Brown 1955); the sixth most abundant of 23 species in the river in 1974 (Harrell 1978); and one of the least abundant of 16 species in 1989 (Garrett *et al.* 1992). Recent information from Cantu and Winemiller (1997) indicates that the species was still present in the Devils River at the confluence with Dolan Falls in 1994, but only in low numbers (thirteenth most abundant of 27 species). The four collections by Cantu and Winemiller (1997) were extensive surveys over 1 year at the one site near Dolan Falls. Even with this increased effort, only 28 individuals of Devils River minnow, out of 4,470 total fish, were documented. No voucher specimens were maintained to verify these collections.

The decline in abundance within the Devils River can best be documented from collections at the site at Baker's Crossing. Over 60 individuals were collected there in 1953, only one was collected in 1989, and none were collected in 1997.

No Devils River minnow were collected in November 1997, by the TPWD from several locations on the Devils River from Pecan Springs downstream to Finegan Springs, just above Dolan Falls (Gary Garrett, TPWD, *in litt.* 1997). New information received

after the proposed rule from additional surveys in 1998 found populations of Devils River minnow in Phillips Creek and Dolan Creek (Gary Graham, TPWD, *in litt.* 1998). Phillips Creek is a very small intermittent tributary to the Devils River that enters from the east, south of Baker's Crossing. No previous collections are recorded from Phillips Creek. Sampling in May 1998, resulted in the collection of about 142 individuals, or about 10 percent of the fishes collected, and was fourth most abundant of the eleven species collected. Despite numerous collection efforts in Dolan Creek, only one individual had previously been collected in this tributary to the Devils River. Sampling in May 1998, resulted in the collection of about 12 individuals.

The Conservation Agreement and subsequent commitments were designed to monitor and improve populations of Devils River minnow in the Devils River. By September 2000, we will establish more (than the two currently known) locations of Devils River minnow in the Devils River with population sizes at least equal to historical levels (such as that found by H.L. Harrell in the 1970's). Threats will be assessed and potential limiting factors in this system addressed, particularly the effects of smallmouth bass and changes in stream flows.

#### San Felipe Creek

San Felipe Creek constitutes the second largest segment of remaining habitat for Devils River minnow in Texas. Brune (1981) lists San Felipe Springs (including ten separate spring sources) as one of the four largest springs in Texas. Devils River minnow previously occurred in two areas on this stream. The upper area is associated with a series of springs, Head and Lowe springs, several miles upstream of the City of Del Rio, and the lower area is associated with two large springs in Del Rio.

In 1979, Devils River minnow made up about 2 percent of all collections (total of 3,458 fish), and was the seventh most abundant of 16 species in the upper portion of San Felipe Creek. In 1989, no Devils River minnow were collected from this site (Garrett *et al.* 1992). No known collections have been made in this area since 1989. This area of San Felipe Creek (upstream of Del Rio) is privately owned and no information is available to discern why the populations of Devils River minnow in this area have significantly declined. Garrett *et al.* (1992) stated that reduced flow from these springs may have contributed to the reduction in

abundance of Devils River minnow. Any further declines in spring flows due to increased withdrawals could negatively affect the Devils River minnow population in this location.

At San Felipe Springs in the City of Del Rio the fish was very rare (less than 1 percent of 1,651 fish collected, and the tenth most abundant of 12 species collected) in 1989 (Garrett *et al.* 1992). Data from 1997 suggest that the Devils River minnow is common in the San Felipe Springs and the urban section of the creek (about 50 individuals were collected for captive study) (Gary Garrett, TPWD, *in litt.* 1997).

The San Felipe Springs are located within the City of Del Rio and may be threatened with future habitat changes from continued urban development. Brune (1981) shows data supporting that the springs have increased their flow since the filling of Amistad Reservoir. The Reservoir is thought to increase flows from San Felipe Springs because the pool elevation of the reservoir is often higher than that of the spring outlet. This situation places hydrostatic pressure on San Felipe Springs through inundated spring openings within the reservoir (Brune 1981). According to Brune (1981), before the reservoir filled, the springs flowed about 2000 lps (about 70 cfs). Since the reservoir filled, flows at the springs have averaged 135 to 150 cfs (unpublished data from International Boundary and Water Commission, *in litt.* 1997). Both of these flow averages are after withdrawals of water by the City of Del Rio for municipal use.

The City of Del Rio draws water directly from San Felipe Springs, which are the sole source of the City's municipal water supply as well as for Laughlin Air Force Base. During 1995 and 1996 the average water use by the City varied seasonally from about 8 to 19 million gallons per day (about 12 to 29 cfs). The expected population growth of Del Rio is projected to be low, 0.5 to 1 percent annually (B. Eby, City of Del Rio, pers. comm., 1997). The City is currently planning to upgrade their water treatment facility and provide a maximum of 20 million gallons per day (about 31 cfs) for municipal use (U.S. Environmental Protection Agency, Finding of No Significant Impact, *in litt.* 1998; O.J. Valdez, Malcom Pirnie, Inc., pers. comm., 1999). This new treatment plant and associated facilities will provide some water conservation because the existing system of water distribution and storage leaks significantly. With additional water conservation measures in place to reduce per capita water use, the City could decrease its water consumption from San Felipe Creek in the future.

Water quality and contamination are inherent threats to the population in San Felipe Creek because of the urban setting. Recent studies by the Texas Natural Resource Conservation Commission (TNRCC; 1994) found elevated levels of nitrates, phosphates and orthophosphate in San Felipe Creek, indicating potential water quality problems. Land uses in the immediate area of the springs, such as runoff from the municipal golf course, may be contributing to these conditions. Other threats from catastrophic events such as contaminant spills could adversely affect the species.

The stream channel of San Felipe Creek in Del Rio has been modified to a limited extent for bank stabilization and public access. In some areas these actions may have limited the available habitat for Devils River minnow.

Based on the current abundance of the Devils River minnow in San Felipe Creek, it appears that existing practices that could impact the aquatic habitat are not yet serious enough to significantly reduce the local population. Aquatic habitat conservation measures (such as water use conservation and water quality protection) in this section of San Felipe Creek could help ensure survival of the species there.

In August 1998, San Felipe Creek experienced a very large flood, with flows estimated at over 100,000 cfs. This was the largest estimated peak flow on record (previous high was about 69,500 cfs). Although the Devils River minnow is adapted to withstand floods (Harrell 1978), the effects of this event are unknown as no collections have been made since the flood.

As part of the Conservation Agreement, by September 2000, we agreed to improve the status of the Devils River minnow in San Felipe Creek by maintaining stable populations at Del Rio and restoring Devils River minnow in the headwater springs area at levels at least equal to historical population sizes. In addition, a finalized policy by the City of Del Rio for preservation of the San Felipe Creek watershed, development of a San Felipe Creek floodplain restoration plan (as response to the flood of August 1998), completion of a water conservation plan, and completion of a management plan for the golf course will reduce threats to the species.

Other actions that may aid in conserving the Devils River minnow include reducing per capita water consumption, seeking alternative sources of water, preserving water quality, educating the public on the importance of the creek, and limiting population density adjacent to the

creek. In addition, the City has agreed to consider the needs of the Devils River minnow and its habitat in the reconstruction of those portions of the creek that were damaged in the August 1998 flooding. These actions together will provide an opportunity to protect the existing populations and expand the available habitat for Devils River minnow in San Felipe Creek.

#### Sycamore Creek

Sycamore Creek constitutes a relatively small portion of the range of the species. There is only one published account of Devils River minnow in this stream from one site, at the State Highway 277 crossing near the Rio Grande River (Garrett *et al.* 1992). Harrell (1980) references the species' occurrence there from an unpublished collection in the early 1970's (H. Harrell, pers. comm. 1997). Garrett *et al.* (1992) found only one individual of Devils River minnow at this location.

Sycamore Creek is an ungaged stream, and there is little information available on habitat conditions. However, the Devils River minnow in this stream is evidently very rare and faces increased risk of extirpation because of the apparent small population size. Devils River minnow in Sycamore Creek likely face potential threats from drought and habitat modification (Garrett *et al.*, 1992). The Conservation Agreement is intended to restore Devils River minnow to Sycamore Creek and/or Las Moras Creek by September 2000. This effort will necessitate further assessment of limiting factors, threat abatement, and landowner cooperation.

#### Las Moras Creek

Las Moras Creek represents the eastern extent of the range of the species. Although the populations there may have been restricted to the spring area in Brackettville, the number of fish in historical collections was relatively large (54 individuals were collected in 1953) (Hubbs and Brown 1956). The natural spring system in Brackettville that supports Las Moras Creek is the location of the earliest collection of Devils River minnow. The species has not been collected from these springs since the 1950's and is believed to be extirpated from that stream, based on several sampling efforts in the late 1970's and 1980's (Smith and Miller 1986; Hubbs *et al.* 1991; Garrett *et al.* 1992).

Habitat for the Devils River minnow was lost when the spring was altered by damming the outflow and removing streambank vegetation to create a recreational swimming pool. Garrett *et al.* (1992) reported that the creek

smelled of chlorine, indicating that the swimming pool may be maintained with chlorination (a toxin to fish). Garrett *et al.* (1992) also indicate that spring flow has been drastically reduced by drought and diversion of water for human consumption. The springs apparently ceased flowing in the 1960's and again in the 1980's (Garrett *et al.* 1992). This combination of habitat loss and alteration and the resulting water quality problems appears to be the most likely cause for the apparent extirpation of the species from Las Moras Creek. The Conservation Agreement is intended to restore Devils River minnow to Las Moras Creek and/or Sycamore Creek by September 2000. This effort will necessitate further assessment of limiting factors, threat abatement, and landowner cooperation.

#### Mexico

The only known historical locations of the Devils River minnow in Mexico are in the Rio San Carlos and three upper streams of the Rio Salado drainage. The Rio San Carlos is a small tributary of the Rio Grande located 27 km (17 mi) south of Ciudad Acuna. Only a few individuals have been collected from this location, once in 1968 (University of Michigan Museum specimens, unpublished data, 1997) and again in 1974. The species has not been collected from this site since 1974 and its status there is unknown (S. Contreras-Balderas, University of Nuevo Leon, *in litt.* 1997).

The population of Devils River minnow in the Rio Salado drainage of northern Mexico represents a critical portion of the southern-most extent of the range. The Rio Salado is a tributary of the Rio Grande and is geographically distinct from the tributaries where the fish occurs in Texas. Collections of the species are limited to the Rio Sabinas, Rio San Juan, and Rio Alamo from about 8 km (5 mi) northwest of Muzquiz to about 12 km (7 mi) west of Nueva Rosita (S. Contreras-Balderas, University of Nuevo Leon, *in litt.* 1997). Therefore, the known range of the species in the Rio Salado is about 30 km (20 mi). The most recent collections of Devils River minnow (31 individuals) from this area were in 1994 (S. Contreras-Balderas, University of Nuevo Leon, *in litt.* 1997).

The Conservation Agreement includes the survey of Mexican streams that could potentially contain populations of Devils River minnow by September 2000. The likely condition of aquatic habitats in the Rio Salado Drainage in Mexico is extremely poor. Contreras and Lozano (1994) report that aquatic ecosystems in this region of Mexico face significant threats due to groundwater

and surface water withdrawals, as well as air and water pollution. Watersheds in northern Mexico have been heavily impacted by land uses and industrial development (S. Contreras-Balderas, University of Nuevo Leon, *in litt.* 1997). The Rio Sabinas, in particular, has been noted for decreasing flows; and spring systems within Coahuila have been extensively exploited (Contreras and Lozano 1994). Contreras-Balderas (1987) considered the Devils River minnow in danger of extinction, and the species is currently listed by the Mexican government as endangered.

#### Range-Wide

Habitat loss and modification throughout a significant portion of the range of the Devils River minnow has resulted in both the fragmentation and contraction of the range of the species. The previous occurrences of known localities of Devils River minnow in Texas can be grouped into nine geographic areas, primarily associated with spring systems—five areas in the Devils River (lower Devils River, Dolan Falls, Baker's Crossing, Pecan Springs, Juno to Beaver Lake); two areas in San Felipe Creek (headwater springs and Del Rio); one area in Sycamore Creek; and one area in Las Moras Creek.

Of these nine areas, the best available information confirms the existence of Devils River minnow in only Phillips Creek downstream from Baker's Crossing, Dolan Creek (about 20 km away from Phillips Creek), and San Felipe Creek in Del Rio. The known existence of only three localities, with one in an urban setting, makes the status of the species in the U.S. tenuous. However, actions in the Conservation Agreement implemented to date, plus future actions to be implemented according to an agreed-upon schedule, leads us to determine that threatened status is appropriate. Although detailed information is limited regarding the status of the species in Mexico, its legal status and degradation of aquatic habitats indicate it is endangered with extinction in that country.

#### B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overutilization is not considered a significant threat to the Devils River minnow. However, there is a potential for impacts should this species be harvested as a baitfish (either commercially or non-commercially).

#### C. Disease or Predation

The Devils River minnow may be affected by the presence of introduced fishes within its range. Of special

concern is the threat of predation by smallmouth bass, a game fish introduced to Amistad Reservoir in about 1975. The smallmouth bass is native to eastern North America but has been widely introduced as a sport fish to reservoirs and streams outside its natural range. It is believed smallmouth bass gained access to the upper portions of the Devils River (upstream of Dolan Falls) in the early to mid-1980's (Gary Garrett, TPWD, pers. comm. 1997). This species is now the dominant predator in the fish community of the Devils River. The TPWD is currently managing the Devils River as a trophy smallmouth bass fishery with size and catch limits.

The Devils River minnow evolved in the presence of native fishes that consume other fishes, such as channel catfish (*Ictalurus punctatus*) and largemouth bass (*Micropterus salmoides*). The Devils River minnow has adapted to persist with these species. However, smallmouth bass are not native, are aggressive predators, and are known to impact other native fish communities (Taylor *et al.* 1984, Moyle 1994). The Devils River minnow is within the size class of small fishes that are susceptible to predation by smallmouth bass. The scarcity of Devils River minnow in the Devils River (where smallmouth bass are prominent) and the abundance of Devils River minnow in San Felipe Creek (where smallmouth bass are not known to occur) provides circumstantial evidence of the likely impacts of this introduced predator. In addition, the small creeks where the Devils River minnow were recently found (Phillips and Dolan creeks) are also not known to contain smallmouth bass. The establishment of smallmouth bass in San Felipe, Phillips, or Dolan creeks is another potential threat to Devils River minnow in those locations.

The tenth action in the Conservation Strategy includes a determination of the interactions between smallmouth bass and Devils River minnow. If results indicate that smallmouth bass are likely having negative effects on Devils River minnow populations, actions such as localized smallmouth bass removal efforts in conjunction with reintroductions of Devils River minnow will be considered. Long-term management of smallmouth bass in the Devils River will be addressed through regulations on catch and size limits to reduce abundance and modify population structures.

#### D. The Inadequacy of Existing Regulatory Mechanisms

The Devils River minnow is listed as a threatened species by the State of

Texas. This provides some protection from collecting, as a permit is required to collect listed species in Texas. However, there are no State or local regulations to protect habitat for the conservation of the species. In addition, no regulations exist to prevent unintentional releases of exotic species by the baitfish industry and anglers.

Limited State regulations administered by the TNRCC serve to protect in-stream flows for surface water rights and water quality for wildlife and human uses. However, these regulations were not designed to conserve habitat for native fishes and currently no minimum in-stream flows are required on streams where Devils River minnow occur.

Surface water rights along the Rio Grande in Texas and its U.S. tributaries are administered by the State of Texas. Groundwater withdrawals that could be affecting stream flows within the range of the Devils River minnow are unregulated. Texas courts have held that, with few exceptions, landowners have the right to take all the water that can be captured under their land (rule of capture). Therefore, there is little opportunity to protect groundwater reserves within existing regulations.

State Water Quality Standards, though primarily concerned with protecting human health, may provide some protection to the Devils River minnow and its habitat. However, the sensitivity of Devils River minnow to any contaminants or water quality changes is unknown and could require more stringent standards than used for human health. The classification of the Devils River and San Felipe Creek under the Texas Surface Water Quality Standards requires maintenance of existing water quality. Sycamore and Las Moras creeks are not classified under these standards.

#### *E. Other Natural or Manmade Factors Affecting Its Continued Existence*

Habitat loss throughout the range of the Devils River minnow has reduced the number of known locations to as few as three. The Devils River minnow is currently known to be common in only two locations, Phillips Creek and San Felipe Creek in Del Rio. However, actions identified in the Conservation Agreement that have been implemented to date have reduced the threat of extinction of the Devils River minnow.

If Devils River minnow still occurs in other locations (such as Sycamore Creek, headwaters of San Felipe Creek, and the Devils River), the number of fish may be too small to constitute viable populations (Caughley and Gunn 1996). Small populations can lead to genetic erosion through inbreeding and are

vulnerable to loss from random natural events, including population fluctuations (Meffe 1986). The Conservation Agreement is intended to improve population levels and distribution of Devils River minnow throughout its range to reduce these threats.

The construction of Amistad Dam has separated the two primary populations of Devils River minnow in Texas (Devils River and San Felipe Creek). This population fragmentation could have significant conservation implications (Gilpin 1987). Determining and monitoring the genetic structure of the different Devils River minnow populations will be needed to ensure the necessary genetic variation within and among populations is not lost (Meffe 1986; Minckley *et al.* 1991).

Recent collections in 1997 from San Felipe Creek revealed for the first time the presence of armored catfish (*Hypostomus* sp.) (Gary Garrett, TPWD, *in litt.* 1997). This fish is an exotic species that has established a breeding population in the San Antonio River, Texas, and was cited as potentially competing with other *Dionda* species due to its food habitats (Hubbs *et al.* 1978). Although *Dionda* species are common in spring runs in Central Texas, they are now absent from these habitats in the San Antonio River, implying the potential displacement by the armored catfish (R.J. Edwards, University of Texas-Pan American, *in litt.* 1998). This could be a threat to Devils River minnow populations in San Felipe Creek.

The future release (intentional or unintentional) of other fishes into areas inhabited by Devils River minnow is another potential threat. Live bait fish are commonly discarded into nearby waters by anglers, resulting in introductions of non-native species. This situation has occurred in many streams in the southwestern U.S. with considerable impacts to the native fish community (Moyle 1994). In addition, exotic fishes from aquariums could be introduced into local waters. Currently, only a small number of introduced fishes occur within the range of the Devils River minnow, but the potential for unintentional introductions is high because of the number of anglers on the Devils River and the urban setting of San Felipe Creek. Threats to the populations of Devils River minnow from possible introduction and establishment of non-native fishes include diseases, parasites, competition for food and space, predation, and hybridization. The Conservation Agreement has provisions for assessment and monitoring of exotic

fishes throughout the range of the Devils River minnow.

The overall decline in abundance of Devils River minnow could be the result of several cumulative factors. For example, subtle changes in stream flows could produce small shifts in habitat use that make the species more vulnerable to competition and predation by native predators and non-native smallmouth bass. In addition, long-term drought could have an effect on the habitat of the species, particularly when combined with impacts of human water use. This species has adapted to historical natural climatic variations (such as large floods and prolonged droughts). However, in conjunction with other threats to the species (primarily existing habitat loss and exotic predators), a drought could significantly increase the threat of extinction. The use of water supplies for human needs (municipal or agricultural) serves to worsen the effects of drought on the natural environment.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to make this final rule. Therefore, based on this evaluation, the most appropriate action is to list the Devils River minnow as threatened. The species currently inhabits a very limited range and the best scientific information available indicates a significant decline in range and abundance of the species.

Some new information was received since the proposal that suggested habitat loss in the upper reaches of the Devils River may be less severe than originally thought. This is because we originally characterized the habitat as historically a continuous flowing stream, when this upper reach may always have been intermittent; therefore, the habitat may have never been more than marginal. In addition, the discovery of two additional localities of Devils River minnow in tributaries to the Devils River provided information that populations are extant in the Devils River drainage. New information was also provided showing the presence of an additional exotic species in San Felipe Creek that presents a threat not mentioned in the proposed rule.

The Conservation Agreement involving us, the TPWD, and the City of Del Rio provides commitments to work toward the recovery of the species through implementing the 10 actions described in the Conservation Strategy (see "Background" section of this rule). In addition, we have received confirmation from both TPWD and the City of Del Rio of their commitment to implement certain key actions of the



Agreement within the first two years of its signing. However, we can still only confirm three localities where the species remains in the U.S.; habitat loss has been considerable in the Devils River due to Amistad Dam and in Las Moras Creek; and the Conservation Agreement has not yet been fully implemented.

An endangered species is defined under the Act as one that is in danger of extinction throughout all or a significant portion of its range. A threatened species is one that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. We have carefully examined the best scientific and commercial information available, and determine that threatened status is appropriate for the Devils River minnow.

### **Critical Habitat**

Critical habitat is defined in section 3 of the Act as—(i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection and; (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. “Conservation” as defined in section 3(3) of the Act means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)) state that designation of critical habitat is not prudent when one or both of the following situations exist—(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species, or (2) such designation of critical habitat would not be beneficial to the species. We find that the designation of critical habitat for the Devils River minnow is not prudent due to lack of benefit.

The section 7 prohibitions against adverse modification of critical habitat apply to Federal actions only (see the “Available Conservation Measures”

section of this rule). The watersheds in the U.S. in which the Devils River minnow occurs are almost entirely in private ownership, and no significant Federal actions affecting the species’ habitat are likely to occur in the area. Therefore, the designation of critical habitat would provide little, if any, benefit to the species through section 7 of the Act.

In addition, any Federal action that would cause adverse modification of critical habitat for the Devils River minnow likely would also cause jeopardy for areas where the species is known to occur. Under section 7, actions funded, authorized, and carried out by Federal agencies may not jeopardize the continued existence of a species or result in the destruction or adverse modification of critical habitat. To “jeopardize the continued existence” of a species is defined as an action that appreciably reduces the likelihood of its survival and recovery (50 CFR part 402). “Destruction or adverse modification of critical habitat” is defined as an appreciable reduction in the value of critical habitat for the survival and recovery of a species. Common to both definitions is an appreciable detrimental effect to both the survival and recovery of a listed species. In biological terms and in consultation practice, the jeopardy standard and the adverse modification standard are virtually identical for areas occupied by the species.

For any listed species, an analysis to determine jeopardy under section 7(a)(2) would consider impacts to the species resulting from impacts to habitat. Therefore, an analysis to determine jeopardy would include an analysis closely parallel to an analysis to determine adverse modification of critical habitat. A Federal action that would adversely modify the species’ habitat would also jeopardize the species (and vice versa). Specifically for the Devils River minnow, any modification to suitable habitat within the species’ range also will substantially affect the species. Actions that may affect the habitat of the Devils River minnow include, but are not limited to—(1) Reduction of water flows from springs or streams, (2) Degradation of water quality, (3) Alteration of shallow, fast-flowing stream areas downstream from the outflow of springs, and (4) Construction of structures that interfere with instream movement of fishes. Given the imperiled status and narrow range of the Devils River minnow, it is likely that any Federal action that would destroy or adversely modify the species’ critical habitat would also jeopardize its continued existence.

Apart from section 7, the Act provides no additional protection to lands designated as critical habitat. Designating critical habitat does not create a park or preserve, and does not require or create a management plan for the areas where the species occurs; does not establish numerical population goals or prescribe specific management actions (inside or outside of critical habitat); and does not have a direct effect on areas not designated as critical habitat. A designation of critical habitat that includes private lands would only affect actions where a Federal nexus (such as Federal funding, authorization, or permit) is present and would not confer any substantial conservation benefit beyond that already provided through section 7 consultation.

Because the Devils River minnow is predominantly found in streams flowing through private lands, the cooperation of private landowners is imperative to conserve the Devils River minnow. Designation of critical habitat on private lands could result in a detriment to the species. The regulatory effect of critical habitat designation is often misunderstood by private landowners, particularly those whose property boundaries are included within a general description of critical habitat for a species. In the past, landowners have mistakenly believed that critical habitat designation would prevent development and impose restrictions on the use of their private property. In some cases, landowners have believed that critical habitat designation is an attempt by the government to confiscate their private property. This misconception was evident from public comments received in 1980 on the proposed designation of critical habitat for the Devils River minnow. Several citizens indicated they strongly believed that by designating critical habitat, the Federal government would have the right to trespass on private property, control private land management actions, and even take ownership of private land for the species. As a result of this misunderstanding, fear of critical habitat designation has sometimes reduced private landowner cooperation in efforts to conserve species listed in Texas. For example, fear resulting from talk of possible designation of critical habitat for the golden-cheeked warbler (*Dendroica chrysoparia*) reduced private landowner cooperation in the management of the species. In addition, in the past landowners have specifically denied access to study sites for Devils River minnow (Hubbs and Garrett 1990, Garrett et al. 1992) due to fears of regulation.

Critical habitat designation can sometimes serve to highlight areas that may be in need of special management considerations or protection. However, in the case of the Devils River minnow the TPWD and local landowners are already aware of the areas in need of special management considerations or protection. Because this species was previously proposed for listing in 1978, and critical habitat proposed in 1980 (due to amendments to the Act both proposals were withdrawn on September 30, 1980 (45 FR 64853)), the public has been aware of the distribution of the species and need for conservation for over 20 years. Prior to and following publication of the 1998 proposed rule to list the Devils River minnow (critical habitat was not prudent in the 1998 proposal (63 FR 14885)), we initiated an extensive public outreach effort to inform and educate the general public and interested parties within the range of the species. We sent out press releases to local newspapers, contacted elected officials, Federal, State, and county agencies, and interested parties, including private landowners. A public hearing was held in 1998, with over 40 people from the local public in attendance. The hearing included the sharing of information on areas important to the species. In addition, over the last two years, TPWD has participated in at least three meetings with affected private landowners (more than 30 individuals in attendance at each meeting) to inform them of the need for conservation of the species, as part of the development of the Conservation Agreement with the State and the City of Del Rio.

We have evaluated the potential notification and education benefit offered by critical habitat designation and find that, for the Devils River minnow, there would be no additional benefit over the outreach associated with the proposal, current outreach for this final rule and interagency coordination processes currently in place. Notification and education can be conducted more effectively by working directly with landowners and communities through the recovery implementation process and, where a Federal nexus exists, through section 7 consultation and coordination. Critical habitat designation for the Devils River minnow would provide no additional notification or education benefit.

In summary, we have determined that the designation of critical habitat for the Devils River minnow would not be beneficial to the species. For the Devils River minnow, the section 7 consultation process will produce a

jeopardy analysis similar to an adverse modification analysis for critical habitat. We have already provided private landowners and State and Federal agencies with up-to-date information on important areas for the Devils River minnow and we plan to continue to do so. Finally, even if designation of critical habitat for the Devils River minnow would provide some small, incremental benefit to the species, that benefit is outweighed by the possible reduction in landowner cooperation that would facilitate the management and recovery of this species. Based on this analysis, we conclude that designation of critical habitat for the Devils River minnow is not prudent.

#### Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation actions by Federal, State, and local agencies, private organizations, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing these interagency cooperation provisions of the Act are codified at 50 CFR part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat, if any has been designated. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Although few Federal agency actions are anticipated, examples of those that may require consultation as described in the preceding paragraph include U.S. Army Corps of Engineers review and approval of activities such as the construction of roads, bridges, and dredging projects subject to section 404 of the Clean Water Act (33 U.S.C. 1344 *et seq.*) and section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 *et seq.*) and U.S. Environmental Protection Agency authorization of discharges under the National Pollutant Discharge

Elimination System. Other Federal agencies whose actions could require consultation include the Department of Defense, NRCS, the Federal Highways Administration, and the Department of Housing and Urban Development.

In addition, section 7(a)(1) of the Act requires all Federal agencies to review the programs they administer and use these programs in furtherance of the purposes of the Act. All Federal agencies, in consultation with the Service, are to carry out programs for the conservation of endangered species and threatened species listed pursuant to section 4 of the Act.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. The prohibitions, codified at 50 CFR 17.31, in part, make it illegal for any person subject to the jurisdiction of the U.S. to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits are described in 50 CFR 17.22, 17.23, and 17.32. Such permits are available for scientific purposes, for the enhancement or propagation or survival of the species, or for incidental take in connection with otherwise lawful activities. For threatened species, there are also permits for zoological exhibition, educational purposes, or special purposes consistent with the purposes of the Act. Information collections associated with these permits are approved under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and assigned Office of Management and Budget clearance number 1018-0094. For additional information concerning these permits and associated requirements, see 50 CFR 17.32.

It is our policy (59 FR 34272) to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of the listing on proposed and ongoing activities within a species' range. We

believe that, based on the best available information, the following actions will not likely result in a violation of section 9:

(1) Normal livestock grazing and other standard ranching practices, such as improving rangeland native grass cover, that do not destroy or degrade Devils River minnow habitat;

(2) Riparian restoration activities that improve the ecological health of native riparian zones along streams and springs, as long as construction activities do not impair Devils River minnow habitat;

(3) Recreational activities such as swimming, canoeing, and fishing, as long as non-native fish or other exotic organisms are not used as bait and released to the stream, and the activities are conducted in such a way as to not damage habitat or negatively affect water quality; and

(4) Actions that may affect Devils River minnow and are authorized, funded or carried out by a Federal agency when the action is conducted in accordance with an incidental take statement issued by us pursuant to section 7 of the Act.

Activities we believe could potentially harm the Devils River minnow and result in "take" include, but are not limited to:

(1) Unauthorized collecting or handling of the species;

(2) Any activities that may result in destruction or significant alteration of habitat occupied by Devils River minnow including, but not limited to, the discharge of fill material, the diversion or alteration of spring and stream flows or withdrawal of groundwater to the point at which Devils River minnow are harmed, and the alteration of the physical channels within the spring runs and stream segments occupied by the species;

(3) Discharge or dumping of pollutants such as chemicals, silt, household or industrial waste, or other material into the springs or streams occupied by Devils River minnow or

into areas that provide access to the aquifer and where such discharge or dumping could affect water quality in spring outflows;

(4) Herbicide, pesticide, or fertilizer application in or near the springs and/or stream segments containing the species;

(5) Introduction of certain non-native species (fish, plants, and other) into occupied habitat of the Devils River minnow or areas connected to these habitats; and

(6) Actions that may affect Devils River minnow and are authorized, funded or carried out by a Federal agency when the action is not conducted in accordance with an incidental take statement issued by us pursuant to section 7 of the Act.

In the descriptions of activities above, a violation of section 9 would occur if those activities occur to an extent that would result in "take" of Devils River minnow. Not all of the activities mentioned above will result in violation of section 9 of the Act; only those activities that result in "take" of Devils River minnow would be considered violations of section 9. We recognize that a wide variety of activities would not harm the species, even if undertaken in the vicinity of the species' habitat. Questions regarding whether specific activities would likely constitute a violation of section 9 should be directed to the Field Supervisor, Austin Ecological Services Field Office (see **ADDRESSES** section). Requests for copies of the regulations regarding listed wildlife and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Region 2, Division of Endangered Species, P.O. Box 1306, Albuquerque, New Mexico 87103-1306 (telephone 505-248-6920; facsimile 505-248-6788).

#### National Environmental Policy Act

We have determined that Environmental Assessments and Environmental Impact Statements, as

defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining our reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 CFR 49244).

#### References Cited

A complete list of all references cited herein, as well as others, is available upon request from the Austin Ecological Services Field Office (see **ADDRESSES** section).

Author: The primary author of this final rule is Nathan Allan, Fish and Wildlife Service (see **ADDRESSES** section).

#### List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

#### Regulation Promulgation

Accordingly, part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, is amended as set forth below:

#### PART 17—[AMENDED]

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

**Authority:** 16 U.S.C. 1361-1407; 16 U.S.C. 1531-1544; 16 U.S.C. 4201-4245; Pub. L. 99-625, 100 Stat. 3500, unless otherwise noted.

2. Amend section 17.11(h) by adding the following, in alphabetical order under "FISHES" to the List of Endangered and Threatened Wildlife to read as follows:

#### § 17.11 Endangered and threatened wildlife.

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*		*	*
FISHES							
*	*	*	*	*		*	*
Minnow, Devils River	<i>Dionda diabolis</i> .....	U.S.A. (TX), Mexico	Entire .....	T	669	NA	NA
*	*	*	*	*		*	*

Dated: September 30, 1999.

**Jamie Rappaport Clark,**

*Director, Fish and Wildlife Service.*

[FR Doc. 99-27188 Filed 10-19-99; 8:45 am]

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Wednesday  
October 20, 1999

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## Part III

# Department of Education

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34 CFR Part 602

The Secretary's Recognition of  
Accrediting Agencies; Final Rule

## DEPARTMENT OF EDUCATION

## 34 CFR Part 602

RIN 1845-AA09

**The Secretary's Recognition of Accrediting Agencies**

AGENCY: Department of Education.

ACTION: Final regulations.

**SUMMARY:** The Secretary amends the regulations governing the Secretary's recognition of accrediting agencies to implement provisions added to the Higher Education Act of 1965, as amended (HEA), by the Higher Education Amendments of 1998. The Secretary recognizes accrediting agencies to assure that those agencies are, for HEA and other Federal purposes, reliable authorities regarding the quality of education or training offered by the institutions or programs they accredit.

**DATES:** These regulations are effective July 1, 2000.

**FOR FURTHER INFORMATION CONTACT:** Karen W. Kershenstein, U.S. Department of Education, 400 Maryland Avenue, SW., room 3012, ROB-3, Washington, DC 20202-5244. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

**SUPPLEMENTARY INFORMATION:** The regulations in this document were developed through the use of negotiated rulemaking. Section 492 of the Higher Education Act requires that, before publishing any proposed regulations to implement programs under Title IV of the Act, the Secretary obtain public involvement in the development of the proposed regulations. After obtaining advice and recommendations, the Secretary must conduct a negotiated rulemaking process to develop the proposed regulations. All proposed regulations must conform to agreements resulting from the negotiated rulemaking process unless the Secretary reopens that process or explains any departure from the agreements to the negotiated rulemaking participants.

These regulations were published in proposed form in the **Federal Register** on June 25, 1999 (64 FR 34466) in conformance with the consensus of the negotiated rulemaking committee. Under the committee's protocols,

consensus meant that no member of the committee dissented from the agreed-upon language. The Secretary invited comments on the proposed regulations by August 24, 1999, and several comments were received. An analysis of the comments and of the changes in the proposed regulations follows.

In the preamble to the notice of proposed rulemaking (NPRM), we discussed the changes we proposed to improve the accrediting agency recognition process. The major changes included the following:

- Revising and reordering the standards accrediting agencies must have.
- Providing a maximum timeframe for agencies to come into compliance with the criteria for recognition (called the "12-month rule").
- Including distance education in the scope of an agency's recognition.

Other proposed changes included in the NPRM were the result of discussion and subsequent consensus among negotiators about how to improve the current regulations by clarifying existing regulatory language and eliminating redundancies.

These final regulations contain several changes resulting from the 26 public comments we received. Most of the changes are clarifications of the regulatory language rather than substantive changes.

We discuss substantive changes under the sections of the regulations to which they pertain. We discuss major issues according to subject, with appropriate sections of the regulations referenced in parentheses. Generally, we do not address technical and other minor changes in the proposed regulations, and do not respond to comments suggesting changes that the Secretary is not authorized by law to make, e.g., requiring accrediting agencies to conduct unannounced inspections. Finally, we do not address comments directed at our processes, such as a comment that the regulations should be revised to say that we will evaluate the consistency of an accrediting agency's application of standards on the basis of "actual fact."

**Analysis of Comments and Changes***Required Accreditation Standards (§ 602.16)*

**Comments:** One commenter believed that the regulations needed to include a definition of "effectively," which appears in 602.16(a)(1). This commenter suggested that the definition state that "input demands cannot override student learning." Another commenter asked what data, factors, or other

elements we will use to determine if an agency's standards effectively address each area for which the agency is required to have a standard.

**Discussion:** We disagree with the alternative language suggested by the first commenter. "Student learning" is extremely important, but it is difficult to assess comprehensively. Furthermore, success with respect to student achievement is only one of the areas for which Congress has mandated that agencies have standards.

While we appreciate the desire for some type of benchmark in the regulations by which to measure the effectiveness of an agency's standards, we believe the issue is quite complex, and any attempt to define the issue thoroughly would be over-regulation at best. Aspects of effectiveness are found in the agency's standards themselves, in the agency's efforts to conduct a systematic program of review that demonstrates that its standards are adequate to evaluate educational quality and relevant to the education and training needs of students, and in the agency's application of its standards, policies, and procedures. As desirable as it might be to try to define "effectiveness" in a manner that encompasses and quantifies all of these perspectives, we believe a more reasoned approach is one of seeking patterns of evidence that, taken collectively, demonstrate effectiveness.

**Change:** None.

*Success With Respect to Student Achievement (§ 602.16(a)(1))*

**Comments:** While several commenters expressed satisfaction with our overall approach to the requirement that agencies have a standard that assesses success with respect to student achievement, one commenter expressed concern that the regulations failed to make student achievement the "touchstone" of accreditation. To remedy this situation, the commenter suggested that this section include a statement that an accrediting agency will not be considered to be a reliable authority regarding educational quality if it denies accreditation to an institution because the institution does not adhere to the agency's input standards even though the institution achieves success with respect to student achievement in relation to its mission. Another commenter felt the regulations needed to make it clear that agencies are not required to measure success with respect to student achievement using a particular assessment strategy.

**Discussion:** As we explained previously, we believe requiring success with respect to student achievement to

override all other areas for which Congress requires agencies to have standards would conflict with the intent of Congress. We agree that agencies should be permitted flexibility in selecting strategies for measuring success with respect to student achievement. We recognize that assessing success with respect to student achievement is a complex, multi-dimensional problem. For this reason, we discussed in the preamble to the NPRM a number of measures that an agency could use, or could require its institutions or programs to use, in the assessment of student achievement. The key, we believe, is the measurement of success with respect to student achievement in relation to institutional mission. Different institutional missions may dictate different measures, and agencies should be free to choose the measure or measures they believe to be best suited to the types of institutions or programs they accredit, provided they can demonstrate that those measures are effective.

*Change:* None.

*The "12-Month" Rule (§§ 602.32 and 602.35)*

*Comments:* We received numerous comments about these sections of the regulations that deal with the provision in the 1998 Amendments to the HEA requiring the Secretary to limit, suspend, or terminate the recognition of an agency if the agency either does not meet the criteria for recognition or is ineffective in its performance with respect to the criteria. Alternatively, the statute permits the Secretary to grant an agency a period of no more than 12 months during which it must come into compliance or demonstrate effectiveness in its performance. If it fails to do so within the specified timeframe, then the statute requires the Secretary to limit, suspend, or terminate the agency's recognition.

Many commenters felt the regulations needed to specify when the 12-month period begins. They also felt that it should begin on the date of the Secretary's decision.

One commenter felt that the regulations needed to define what constitutes good cause. The commenter felt that the regulations should make it clear that the Secretary is expected to grant extensions only for demonstrable exigency and lack of fault and that extensions of the timeframe should be rare and brief.

Many commenters raised questions about how we will review agencies under this provision. In particular, they questioned how some of our previous citations of agencies as being "in need

of strengthening" compliance will be handled under the 12-month rule.

Finally, several commenters expressed the opinion that the regulations should give the National Advisory Committee or the Secretary some latitude in implementing the 12-month rule, either for the benefit of agencies that are trying to improve their processes or to allow agencies to continue to be recognized despite their noncompliance with some of the criteria.

One commenter thought the regulations needed to make it clear that recognized agencies maintain their status as recognized agencies even if they are under a deferral or until a decision on their application for continued recognition has been reached.

*Discussion:* We understand and appreciate the many concerns that commenters, most of whom were affiliated with recognized accrediting agencies, expressed about this new, statutorily mandated provision. We note that some of the concerns are directed toward process, i.e., how we will implement this provision, rather than toward the provision itself, and we generally do not address process in the regulations.

With regard to the issue of when the 12-month period begins, we note that some of the commenters appear to assume that the Secretary must always give agencies 12 months to correct whatever problem caused the Secretary to decide to defer a decision on the agency's application for recognition. That is incorrect. Nevertheless, we believe it would be useful for the regulations to establish clearly that whatever deferral period the Secretary grants, that period begins on the date of the Secretary's deferral decision.

On the issue of defining good cause in the regulations, we note that negotiators carefully considered whether the regulations should define "good cause" and in the end concluded that it was best not to define this term. Instead, the burden rests with an agency that has failed to meet the statutory deadline to demonstrate that good cause exists for the Secretary to grant a request for an extension of time.

With regard to the call for greater flexibility to continue to recognize agencies that are not in full compliance, no change can be made because the statute does not allow for greater flexibility.

Finally, the proposed regulations were intended to convey that a recognized agency maintains its status as a recognized agency even if action on its continued recognition has been deferred or a decision on recognition

has not been reached. Deferral is not a final decision.

*Changes:* We have changed 602.35(b)(3)(iii) to state that the deferral period begins on the date of the Secretary's decision. We have also changed 602.35(d) to clarify that recognition of a recognized agency continues until the Secretary reaches a final decision to approve or deny recognition.

*Distance Education and Scope of Recognition (§ 602.3)*

*Comments:* Several commenters expressed concerns about the inclusion of distance education in the scope of an agency's recognition. Most of their comments focused on whether agencies would have to go through a separate review process before distance education would be included in their scope of recognition, although one commenter asked why distance education, which the commenter described as "just one particular type of instructional methodology," should be included in an agency's scope of recognition.

*Discussion:* The 1998 amendments to the Higher Education Act clearly require us to evaluate distance education accrediting activities as part of the recognition process and to include distance education as a component in determining the scope of an agency's recognition. We do not envision implementing this provision by requiring agencies to go through a separate review process to have distance education included in their scope. Rather, we will observe and evaluate, as part of our regular review of an agency for initial or continued recognition, the agency's compliance with the criteria for recognition, including the agency's compliance in accrediting distance education programs and institutions.

*Change:* None.

*Section 602.3 Definitions*

*Adverse action*

*Comments:* One commenter felt that show cause and probation should be considered adverse actions to allow accrediting agencies to work more effectively with institutions that need more time to improve. In raising this issue, the commenter noted that students are the ones who are hurt most if schools have to close if they lose their accreditation. Another commenter, however, supported the change we proposed that excludes show cause and probation from the term "adverse action."

*Discussion:* We continue to believe that including interim actions such as



probation and show cause as adverse actions would permit a noncompliant institution or program to retain accreditation or preaccreditation well beyond the maximum timeframes the regulations prescribe. It would also put students at risk because the quality of education provided by the institution or program might suffer as a result of the institution's or program's noncompliance with the agency's standards. We believe that the provision in 602.20(b), allowing an agency to extend the timeframe for coming into compliance for good cause, gives the agency the flexibility it needs on a case-by-case basis to deal with situations in which the agency believes there is justification for giving the institution or program more time.

*Change:* None.

#### *Representative of the public*

*Comment:* One commenter expressed concern that the proposed definition does not state that a student may serve as a representative of the public.

*Discussion:* We continue to believe, as we stated in the preamble to the final regulations previously amending this part 602, published April 29, 1994 (59 FR 22250) (the 1994 regulations), that it is useful for agencies to include students and members of their families as representatives of the public. The students are the consumers in this context. However, the definition we proposed in the NPRM, which is the same as the definition in the 1994 regulations, does not preclude selection of students or their family members for this purpose. Therefore, there is no need to change the definition.

*Change:* None.

#### *Vocational Education*

*Comment:* One commenter requested that we add a definition of "vocational education" to 602.3, noting that we mentioned the term in the discussion of success with respect to student achievement in the preamble to the NPRM.

*Discussion:* The term is not used in the regulations. Therefore, there is no need to define it.

*Change:* None.

#### *Section 602.14 Purpose and Organization*

*Comments:* One commenter suggested that recognized agencies be exempt from demonstrating compliance with this section when they apply for continued recognition if they were found to be in compliance the last time they were reviewed and their structure has not changed since then. Another commenter believed that the provisions related to

the waiver of the "separate and independent" requirement nullify the availability of the waiver and are not consistent with the statute.

*Discussion:* We believe the suggestion that recognized agencies not be required to demonstrate compliance with 602.14 when they apply for continued recognition has merit. However, we do not think a regulatory change is needed to implement it. We expect to develop new guidelines for agencies on how to submit petitions for recognition under these regulations, and we will implement this suggestion in those materials.

With respect to the waiver of the "separate and independent" requirement, we disagree with the commenter's conclusion that the regulations are inconsistent with the statute and nullify the availability of the waiver. We note that the regulations on this point remain unchanged from those issued in 1994.

*Change:* None.

#### *Section 602.15 Administrative and Fiscal Responsibilities*

*Comment:* One commenter suggested that the composition of on-site evaluation teams should be reconsidered but offered no specific suggestions for change.

*Discussion:* Even though the commenter provided no specific suggestions, we reconsidered the proposed language in 602.15(a)(3) and (4) governing the composition of an agency's evaluation, policy, and decision-making bodies. We found that the language allowed an agency that accredited a single-purpose institution, such as a freestanding law school, to satisfy the regulations by simply having educators, i.e., *academic and administrative personnel, on these bodies and not any practitioners. While we know that most agencies that accredit single-purpose institutions include practitioners on their evaluation teams, we felt it was important that the regulations require this practice.*

*Change:* We have modified 602.15(a)(4) to require an agency to have educators and practitioners on its evaluation, policy, and decision-making bodies if it accredits programs or single-purpose institutions that prepare students for a specific profession.

#### *Section 602.19 Monitoring and Reevaluation of Accredited Institutions and Programs*

*Comment:* Two commenters expressed concern about the discussion in the preamble of the NPRM about agencies' responsibilities for monitoring accredited institutions and programs

throughout the accreditation period. Specifically, they objected to the statement that an agency's monitoring procedures must provide for prompt and appropriate action by an agency whenever it receives substantial, credible evidence from any reliable source, including the courts, that indicates a systemic problem that calls into question the ability of an institution or program to meet the agency's standards. They also objected to the statement in the preamble that we find it unacceptable for an agency to have as its policy that it will not look at, or take appropriate action based upon, information that comes to its attention through pending third-party litigation. The commenters felt that our position would place the agency in the middle of the litigation.

*Discussion:* The comments are directed to preamble, rather than regulatory, language, so there is no need to make any changes to the regulations. Agencies, under the regulations, have a responsibility to monitor institutions and programs throughout their accreditation period to ensure that educational quality is maintained and to take appropriate action whenever they receive substantial, credible evidence from any reliable source that calls into question the quality of the education or training provided by the institution or program. That obligation applies with respect to information the agency obtains as a result of litigation, just as it applies to information obtained from other sources.

*Change:* None.

#### *Section 602.21 Review of Standards*

*Comments:* Most commenters liked the proposed regulations, which require agencies to maintain a systematic program of review that demonstrates their standards are adequate to evaluate the quality of education or training provided by the institutions and programs they accredit and relevant to the needs of students. Two commenters, however, preferred the language in the 1994 regulations, which required agencies to maintain a systematic program of review that demonstrated their standards were valid and reliable indicators of educational quality. One commenter thought the phrase "relevant to the needs of students" in the proposed regulations should be replaced by the phrase from the 1994 regulations, "relevant to the education and training needs of students," which the commenter believed was more appropriate. Finally, one commenter stated that an agency's standards should not be deemed adequate to evaluate the quality of education or relevant to the

needs of students if they resulted in the denial of accreditation to schools that achieve student success in learning.

*Discussion:* The issue of the validation of standards through the systematic review of an agency's standards was discussed at length during negotiated rulemaking. The ultimate consensus that was reached reflects negotiators' belief that the language in the proposed regulations strikes a balance between overly prescriptive regulation of agencies' standards and processes and a requirement that looks only at an agency's review process and not at the substance of the standards. It also avoids some of the problems encountered with the language in the 1994 regulations that uses the terms "validity" and "reliability," the interpretations of which, when applied in the context of agencies' standards, were often misunderstood and misused.

We believe the comment about the need for agencies to demonstrate that their standards are relevant to the education and training needs of students, not simply the needs of students, has merit. However, we disagree that an agency's standards should not be deemed adequate to evaluate the quality of education or relevant to the needs of students if its standards resulted in the denial of accreditation to schools that achieve student success in learning. Demonstrating success with respect to student achievement is certainly necessary to establishing the adequacy of an agency's standards. By itself, however, such a demonstration is by no means sufficient to ensure the adequacy of those standards.

*Change:* We have changed 602.21(a) to require agencies to maintain a systematic program of review that demonstrates their standards are relevant to the education and training needs of students.

#### *Section 602.21(c) Process for Changing Standards*

*Comment:* Several commenters raised concerns that the proposed regulations require an agency to provide notice about proposed changes to standards only to its relevant constituencies but not to other interested parties. One commenter felt regional accreditors should be required to notify all institutions in their region, while specialized accreditors should be required to provide notice to all institutions that provide education in the field. Another commenter felt the regulations should require agencies to give institutions opportunity and adequate time to respond, with the

knowledge that their comments will be considered. Finally, one commenter felt the requirement for agencies to complete an action to change a standard "within a reasonable period of time" after a problem is found was too vague. The commenter suggested as an alternative that agencies could demonstrate that they have a formal process that allows changes to the standards to occur in a systematic manner.

*Discussion:* During negotiated rulemaking, accreditors readily acknowledged their responsibility to notify persons they knew to be interested, but expressed concern about the burden and cost of providing timely and effective notice to a large number of entities to see if they might have an interest in commenting on proposed changes to their standards. The language negotiators agreed upon was an attempt to find a reasonable solution to the problem. Based on the comments we received, we have reconsidered the matter. We believe the concept of requiring a regional accreditor to notify all institutions in its region of proposed changes to its standards has some merit, but that it imposes a greater burden than necessary to address the concern. A more reasonable approach, we believe, is to require an accrediting agency to provide notice of proposed changes to its standards to all parties who have made their interest known to the agency. This will ensure that all who want notice will get it.

With regard to the comment that the regulations should require agencies to give institutions opportunity and adequate time to respond, we believe the regulations, by stating that agencies must give "adequate opportunity to comment on the proposed changes," already do this.

Finally, we do not believe the phrase "within a reasonable period of time" is too vague. Rather, we believe it provides a degree of flexibility to agencies in establishing schedules for meetings, within a reasonable range.

*Change:* We have added the phrase "and other parties who have made their interest known to the agency" to 602.21(c)(1).

#### *Section 602.22(a)(vii) Substantive Change Procedures for Additional Locations*

*Comments:* Most commenters welcomed the changes to the requirement for mandatory site visits to new sites within 6 months. One commenter, however, wanted us to remove the requirement for a site visit to any additional locations a school establishes.

*Discussion:* We continue to believe that there is need for an accrediting agency to monitor an institution very closely as it begins to operate more than just the main campus. While the need for that close monitoring may diminish once the institution has gained experience in establishing effective systems for the administration of multiple sites, we do not believe that, in general, the addition of a single additional site is sufficient for an institution to be able to demonstrate that it has in place effective mechanisms to administer multiple sites.

*Change:* None.

#### *Section 602.24(b) Change in Ownership*

*Comment:* One commenter stated that the proposed regulations did not address a problem that existed with the 1994 regulations, namely that an agency cannot conduct a site visit unless it is notified of the change in ownership. The commenter suggested requiring agencies to conduct the site visit within 6 months following the change, or notification of the change, whichever comes later.

*Discussion:* The regulations require an agency's definition of substantive change to include any change in the legal status, form of control, or ownership of the institution. The agency's procedures for handling substantive change must also require an institution to obtain the agency's approval before the change is included in its scope of accreditation of the institution. Thus, the situation the commenter describes represents a failure by the school to follow the agency's required procedures and should be dealt with by the agency. No regulatory change is needed. Obviously, an agency can only conduct a site visit if it knows about the change in ownership, and we would not regard the agency as being in violation of the criteria for recognition if it failed to conduct a visit within 6 months of the change solely because it was not informed of the change at the time it occurred.

*Change:* None.

#### *Section 602.24(c)(ii) Teach-outs*

*Comment:* One commenter noted that the location of the closing institution may not be very near other institutions that offer similar programs and suggested that the regulations require the teach-out institution to be as geographically proximate to the closing institution as possible.

*Discussion:* We believe that this provision in the regulations must balance the goal of achieving the most geographically proximate teach-out with

the goal of ensuring, to the extent possible, that a teach-out is offered. Sometimes there is no institution that is as close to the closing institution as we might wish. In other instances, the most geographically proximate institution does not want to provide the teach-out, but another institution is willing to do so even if it is not as close to the closing institution.

We believe the regulations contain the flexibility necessary to best protect students. They address the proximity issue by requiring the teach-out institution to demonstrate that it can provide students access to the program without requiring them to move or travel substantial distances.

*Change:* None.

#### **Section 602.26 Notification of Accrediting Decisions**

*Comments:* One commenter stated that the 24-hour rule for notifying the public of final decisions to place an institution or program on probation or an equivalent status or to deny, withdraw, suspend, revoke, or terminate the accreditation or preaccreditation of an institution or program was unclear. The commenter asked whether this provision meant notifying the public in general, for example, by posting the notice to the agency's web site, or whether it meant telling anyone who happened to call the agency to inquire about the institution or program.

Another commenter suggested that guaranty agencies be included in the notification.

*Discussion:* With respect to the first commenter, we believe the principal issue here is providing effective notice to the public. We believe one way to do this is to post the information to the agency's web site within 24 hours of notifying the institution or program, but there may be other ways. The agency should have the flexibility to decide the approach that suits it best. Certainly the agency should give the information out to anyone who happens to call the agency inquiring about the institution or program after the 24-hour timeframe.

We agree with the commenter who suggested that guaranty agencies should receive notification about accrediting decisions. However, an accrediting agency may not know which guaranty agencies service a particular institution. Accordingly, the Department will establish a process for forwarding this information, upon receipt, to guaranty agencies.

*Change:* None.

#### **Section 602.33 Appeal of an Advisory Committee Recommendation**

*Comments:* One commenter thought that the 10-day timeframe for an agency to file its intent to appeal an Advisory Committee recommendation was too short. The commenter also questioned whether the 10-day timeframe meant 10 calendar days or 10 business days.

*Discussion:* We do not believe the 10-day timeframe to file an intent to appeal an Advisory Committee recommendation is too short. An agency knows the Advisory Committee's recommendation as soon as it is made, and it need only submit a simple declaration of intent to appeal, without any documentation, to meet the 10-day requirement. The regulations permit the agency 30 days to submit the actual appeal, along with any supporting documentation that agency may wish the Secretary to consider.

On the issue of whether the timeframe refers to calendar or business days, we note that all timeframes specified in these regulations follow the same convention as in the previous regulations; namely, they refer to calendar days, not business days.

*Change:* None.

#### **Section 602.42 Appeal of the Subcommittee's Recommendation**

*Comments:* One commenter thought that the selection of a subcommittee of the Advisory Committee to conduct a hearing on whether an agency's recognition should be limited, suspended, or terminated should be done randomly.

*Discussion:* With regard to the composition of the subcommittee, the principal issue is the availability of members to serve. The subcommittee is only convened if Department staff has concluded that an agency fails to comply with the criteria for recognition or is ineffective with respect to those criteria, either of which is a very serious situation and must be dealt with as quickly as possible. Requiring that subcommittee members be selected on a completely random basis, or even on a rotating basis, could jeopardize the Department's ability to convene the subcommittee quickly.

*Change:* None.

#### **Executive Order 12866**

We have reviewed these final regulations in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with these final regulations are those

resulting from statutory requirements and those we have determined to be necessary for a determination that an accrediting agency that seeks recognition is in fact a reliable authority regarding the quality of education or training provided by the institutions or programs it accredits.

In assessing the potential costs and benefits—both quantitative and qualitative—of these final regulations, we have determined that the benefits of the regulations justify the costs.

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

We discussed the potential costs and benefits of these final regulations in the preamble to the NPRM under the headings: Changes From Existing Regulations (64 FR 34467–34473), Paperwork Reduction Act of 1995 (64 FR 34474), and Regulatory Flexibility Act Certification (64 FR 34474).

#### **Paperwork Reduction Act of 1995**

The Paperwork Reduction Act of 1995 does not require accrediting agencies to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. We display the valid OMB control number assigned to the collection of information in these final regulations at the end of the affected sections of the regulations.

#### **Assessment of Educational Impact**

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

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### List of Subjects in 34 CFR Part 602

Colleges and universities, Education, Reporting and recordkeeping requirements.

Dated: October 4, 1999.

**Richard W. Riley,**

*Secretary of Education.*

For the reasons discussed in the preamble, the Secretary amends title 34 of the Code of Federal Regulations by revising part 602 to read as follows:

## PART 602—THE SECRETARY'S RECOGNITION OF ACCREDITING AGENCIES

### Subpart A—General

Sec.

- 602.1 Why does the Secretary recognize accrediting agencies?
- 602.2 How do I know which agencies the Secretary recognizes?
- 602.3 What definitions apply to this part?

### Subpart B—The Criteria for Recognition

Basic Eligibility Requirements

- 602.10 Link to Federal programs.
  - 602.11 Geographic scope of accrediting activities.
  - 602.12 Accrediting experience.
  - 602.13 Acceptance of the agency by others.
- Organizational and Administrative Requirements
- 602.14 Purpose and organization.
  - 602.15 Administrative and fiscal responsibilities.

Required Standards and Their Application

- 602.16 Accreditation and preaccreditation standards.
- 602.17 Application of standards in reaching an accrediting decision.
- 602.18 Ensuring consistency in decision-making.
- 602.19 Monitoring and reevaluation of accredited institutions and programs.
- 602.20 Enforcement of standards.
- 602.21 Review of standards.

Required Operating Policies and Procedures

- 602.22 Substantive change.
- 602.23 Operating procedures all agencies must have.
- 602.24 Additional procedures certain institutional accreditors must have.
- 602.25 Due process.
- 602.26 Notification of accrediting decisions.
- 602.27 Other information an agency must provide the Department.

- 602.28 Regard for decisions of States and other accrediting agencies.

### Subpart C—The Recognition Process

Application and Review by Department Staff

- 602.30 How does an agency apply for recognition?
- 602.31 How does Department staff review an agency's application?

Review by the National Advisory Committee on Institutional Quality and Integrity

- 602.32 What is the role of the Advisory Committee and the senior Department official in the review of an agency's application?
- 602.33 How may an agency appeal a recommendation of the Advisory Committee?

Review and Decision by the Secretary

- 602.34 What does the Secretary consider when making a recognition decision?
- 602.35 What information does the Secretary's recognition decision include?
- 602.36 May an agency appeal the Secretary's final recognition decision?

### Subpart D—Limitation, Suspension, or Termination of Recognition

Limitation, Suspension, and Termination Procedures

- 602.40 How may the Secretary limit, suspend, or terminate an agency's recognition?
- 602.41 What are the notice procedures?
- 602.42 What are the response and hearing procedures?
- 602.43 How is a decision on limitation, suspension, or termination of recognition reached?

Appeal Rights and Procedures

- 602.44 How may an agency appeal the subcommittee's recommendation?
- 602.45 May an agency appeal the Secretary's final decision to limit, suspend, or terminate its recognition?

### Subpart E—Department Responsibilities

- 602.50 What information does the Department share with a recognized agency about its accredited institutions and programs?

**Authority:** 20 U.S.C. 1099b, unless otherwise noted.

### Subpart A—General

#### § 602.1 Why does the Secretary recognize accrediting agencies?

(a) The Secretary recognizes accrediting agencies to ensure that these agencies are, for the purposes of the Higher Education Act of 1965, as amended (HEA), or for other Federal purposes, reliable authorities regarding the quality of education or training offered by the institutions or programs they accredit.

(b) The Secretary lists an agency as a nationally recognized accrediting agency if the agency meets the criteria for recognition listed in subpart B of this part.

**(Authority:** 20 U.S.C. 1099b)

#### § 602.2 How do I know which agencies the Secretary recognizes?

(a) Periodically, the Secretary publishes a list of recognized agencies in the **Federal Register**, together with each agency's scope of recognition. You may obtain a copy of the list from the Department at any time. The list is also available on the Department's web site.

(b) If the Secretary denies continued recognition to a previously recognized agency, or if the Secretary limits, suspends, or terminates the agency's recognition before the end of its recognition period, the Secretary publishes a notice of that action in the **Federal Register**. The Secretary also makes the reasons for the action available to the public, on request.

**(Authority:** 20 U.S.C. 1099b)

#### § 602.3 What definitions apply to this part?

The following definitions apply to this part:

*Accreditation* means the status of public recognition that an accrediting agency grants to an educational institution or program that meets the agency's standards and requirements.

*Accrediting agency or agency* means a legal entity, or that part of a legal entity, that conducts accrediting activities through voluntary, non-Federal peer review and makes decisions concerning the accreditation or preaccreditation status of institutions, programs, or both.

*Act* means the Higher Education Act of 1965, as amended.

*Adverse accrediting action or adverse action* means the denial, withdrawal, suspension, revocation, or termination of accreditation or preaccreditation, or any comparable accrediting action an agency may take against an institution or program.

*Advisory Committee* means the National Advisory Committee on Institutional Quality and Integrity.

*Branch campus* means a location of an institution that meets the definition of branch campus in 34 CFR 600.2.

*Distance education* means an educational process that is characterized by the separation, in time or place, between instructor and student. The term includes courses offered principally through the use of—

- (1) Television, audio, or computer transmission, such as open broadcast, closed circuit, cable, microwave, or satellite transmission;
- (2) Audio or computer conferencing;
- (3) Video cassettes or disks; or
- (4) Correspondence.

*Final accrediting action* means a final determination by an accrediting agency regarding the accreditation or

preaccreditation status of an institution or program. A final accrediting action is not appealable within the agency.

*Institution of higher education or institution* means an educational institution that qualifies, or may qualify, as an eligible institution under 34 CFR part 600.

*Institutional accrediting agency* means an agency that accredits institutions of higher education.

*Nationally recognized accrediting agency, nationally recognized agency, or recognized agency* means an accrediting agency that the Secretary recognizes under this part.

*Preaccreditation* means the status of public recognition that an accrediting agency grants to an institution or program for a limited period of time that signifies the agency has determined that the institution or program is progressing towards accreditation and is likely to attain accreditation before the expiration of that limited period of time.

*Program* means a postsecondary educational program offered by an institution of higher education that leads to an academic or professional degree, certificate, or other recognized educational credential.

*Programmatic accrediting agency* means an agency that accredits specific educational programs that prepare students for entry into a profession, occupation, or vocation.

*Representative of the public* means a person who is not—

(1) An employee, member of the governing board, owner, or shareholder of, or consultant to, an institution or program that either is accredited or preaccredited by the agency or has applied for accreditation or preaccreditation;

(2) A member of any trade association or membership organization related to, affiliated with, or associated with the agency; or

(3) A spouse, parent, child, or sibling of an individual identified in paragraph (1) or (2) of this definition.

*Scope of recognition or scope* means the range of accrediting activities for which the Secretary recognizes an agency. The Secretary may place a limitation on the scope of an agency's recognition for Title IV, HEA purposes. The Secretary's designation of scope defines the recognition granted according to—

(1) Geographic area of accrediting activities;

(2) Types of degrees and certificates covered;

(3) Types of institutions and programs covered;

(4) Types of preaccreditation status covered, if any; and

(5) Coverage of accrediting activities related to distance education, if any.

*Secretary* means the Secretary of the U.S. Department of Education or any official or employee of the Department acting for the Secretary under a delegation of authority.

*Senior Department official* means the senior official in the U.S. Department of Education who reports directly to the Secretary regarding accrediting agency recognition.

*State* means a State of the Union, American Samoa, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau. The latter three are also known as the Freely Associated States.

*Teach-out agreement* means a written agreement between institutions that provides for the equitable treatment of students if one of those institutions stops offering an educational program before all students enrolled in that program have completed the program.

(Authority: 20 U.S.C. 1099b)

## Subpart B—The Criteria for Recognition

### Basic Eligibility Requirements

#### § 602.10 Link to Federal programs.

The agency must demonstrate that—

(a) If the agency accredits institutions of higher education, its accreditation is a required element in enabling at least one of those institutions to establish eligibility to participate in HEA programs; or

(b) If the agency accredits institutions of higher education or higher education programs, or both, its accreditation is a required element in enabling at least one of those entities to establish eligibility to participate in non-HEA Federal programs.

(Authority: 20 U.S.C. 1099b)

#### § 602.11 Geographic scope of accrediting activities.

The agency must demonstrate that its accrediting activities cover—

(a) A State, if the agency is part of a State government;

(b) A region of the United States that includes at least three States that are reasonably close to one another; or

(c) The United States.

(Authority: 20 U.S.C. 1099b)

#### § 602.12 Accrediting experience.

(a) An agency seeking initial recognition must demonstrate that it has—

(1) Granted accreditation or preaccreditation—

(i) To one or more institutions if it is requesting recognition as an institutional accrediting agency and to one or more programs if it is requesting recognition as a programmatic accrediting agency;

(ii) That covers the range of the specific degrees, certificates, institutions, and programs for which it seeks recognition; and

(iii) In the geographic area for which it seeks recognition; and

(2) Conducted accrediting activities, including deciding whether to grant or deny accreditation or preaccreditation, for at least two years prior to seeking recognition.

(b) A recognized agency seeking an expansion of its scope of recognition must demonstrate that it has granted accreditation or preaccreditation covering the range of the specific degrees, certificates, institutions, and programs for which it seeks the expansion of scope.

(Authority: 20 U.S.C. 1099b)

#### § 602.13 Acceptance of the agency by others.

The agency must demonstrate that its standards, policies, procedures, and decisions to grant or deny accreditation are widely accepted in the United States by—

(a) Educators and educational institutions; and

(b) Licensing bodies, practitioners, and employers in the professional or vocational fields for which the educational institutions or programs within the agency's jurisdiction prepare their students.

(Authority: 20 U.S.C. 1099b)

### Organizational and Administrative Requirements

#### § 602.14 Purpose and organization.

(a) The Secretary recognizes only the following four categories of agencies:

The Secretary recognizes . . .	that . . .
(1) An accrediting agency .....	(i) Has a voluntary membership of institutions of higher education;

The Secretary recognizes . . .	that . . .
(2) An accrediting agency .....	(ii) Has as a principal purpose the accrediting of institutions of higher education and that accreditation is a required element in enabling those institutions to participate in HEA programs; and (iii) Satisfies the "separate and independent" requirements in paragraph (b) of this section.
(3) An accrediting agency .....	(i) Has a voluntary membership; and (ii) Has as its principal purpose the accrediting of higher education programs, or higher education programs and institutions of higher education, and that accreditation is a required element in enabling those entities to participate in non-HEA Federal programs. for purposes of determining eligibility for Title IV, HEA programs— (i) Either has a voluntary membership of individuals participating in a profession or has as its principal purpose the accrediting of programs within institutions that are accredited by a nationally recognized accrediting agency; and (ii) Either satisfies the "separate and independent" requirements in paragraph (b) of this section or obtains a waiver of those requirements under paragraphs (d) and (e) of this section.
(4) A State agency .....	(i) Has as a principal purpose the accrediting of institutions of higher education, higher education programs, or both; and (ii) The Secretary listed as a nationally recognized accrediting agency on or before October 1, 1991 and has recognized continuously since that date.

(b) For purposes of this section, the term *separate and independent* means that—

(1) The members of the agency's decision-making body—who decide the accreditation or preaccreditation status of institutions or programs, establish the agency's accreditation policies, or both—are not elected or selected by the board or chief executive officer of any related, associated, or affiliated trade association or membership organization;

(2) At least one member of the agency's decision-making body is a representative of the public, and at least one-seventh of that body consists of representatives of the public;

(3) The agency has established and implemented guide lines for each member of the decision-making body to avoid conflicts of interest in making decisions;

(4) The agency's dues are paid separately from any dues paid to any related, associated, or affiliated trade association or membership organization; and

(5) The agency develops and determines its own budget, with no review by or consultation with any other entity or organization.

(c) The Secretary considers that any joint use of personnel, services, equipment, or facilities by an agency and a related, associated, or affiliated trade association or membership organization does not violate the "separate and independent" requirements in paragraph (b) of this section if—

(1) The agency pays the fair market value for its proportionate share of the joint use; and

(2) The joint use does not compromise the independence and confidentiality of the accreditation process.

(d) For purposes of paragraph (a)(3) of this section, the Secretary may waive

the "separate and independent" requirements in paragraph (b) of this section if the agency demonstrates that—

(1) The Secretary listed the agency as a nationally recognized agency on or before October 1, 1991 and has recognized it continuously since that date;

(2) The related, associated, or affiliated trade association or membership organization plays no role in making or ratifying either the accrediting or policy decisions of the agency;

(3) The agency has sufficient budgetary and administrative autonomy to carry out its accrediting functions independently; and

(4) The agency provides to the related, associated, or affiliated trade association or membership organization only information it makes available to the public.

(e) An agency seeking a waiver of the "separate and independent" requirements under paragraph (d) of this section must apply for the waiver each time the agency seeks recognition or continued recognition.

(Authority: 20 U.S.C. 1099b)

#### § 602.15 Administrative and fiscal responsibilities.

The agency must have the administrative and fiscal capability to carry out its accreditation activities in light of its requested scope of recognition. The agency meets this requirement if the agency demonstrates that—

(a) The agency has—

(1) Adequate administrative staff and financial resources to carry out its accrediting responsibilities;

(2) Competent and knowledgeable individuals, qualified by education and experience in their own right and trained by the agency on its standards,

policies, and procedures, to conduct its on-site evaluations, establish its policies, and make its accrediting and preaccrediting decisions;

(3) Academic and administrative personnel on its evaluation, policy, and decision-making bodies, if the agency accredits institutions;

(4) Educators and practitioners on its evaluation, policy, and decision-making bodies, if the agency accredits programs or single-purpose institutions that prepare students for a specific profession;

(5) Representatives of the public on all decision-making bodies; and

(6) Clear and effective controls against conflicts of interest, or the appearance of conflicts of interest, by the agency's—

(i) Board members;

(ii) Commissioners;

(iii) Evaluation team members;

(iv) Consultants;

(v) Administrative staff; and

(vi) Other agency representatives; and

(b) The agency maintains complete and accurate records of—

(1) Its last two full accreditation or preaccreditation reviews of each institution or program, including on-site evaluation team reports, the institution's or program's responses to on-site reports, periodic review reports, any reports of special reviews conducted by the agency between regular reviews, and a copy of the institution's or program's most recent self-study; and

(2) All decisions regarding the accreditation and preaccreditation of any institution or program, including all correspondence that is significantly related to those decisions.

(Approved by the Office of Management and Budget under control number 1845-0003)

(Authority: 20 U.S.C. 1099b)

## Required Standards and Their Application

### § 602.16 Accreditation and preaccreditation standards.

(a) The agency must demonstrate that it has standards for accreditation, and preaccreditation, if offered, that are sufficiently rigorous to ensure that the agency is a reliable authority regarding the quality of the education or training provided by the institutions or programs it accredits. The agency meets this requirement if—

(1) The agency's accreditation standards effectively address the quality of the institution or program in the following areas:

(i) Success with respect to student achievement in relation to the institution's mission, including, as appropriate, consideration of course completion, State licensing examination, and job placement rates.

(ii) Curricula.

(iii) Faculty.

(iv) Facilities, equipment, and supplies.

(v) Fiscal and administrative capacity as appropriate to the specified scale of operations.

(vi) Student support services.

(vii) Recruiting and admissions practices, academic calendars, catalogs, publications, grading, and advertising.

(viii) Measures of program length and the objectives of the degrees or credentials offered.

(ix) Record of student complaints received by, or available to, the agency.

(x) Record of compliance with the institution's program responsibilities under Title IV of the Act, based on the most recent student loan default rate data provided by the Secretary, the results of financial or compliance audits, program reviews, and any other information that the Secretary may provide to the agency; and

(2) The agency's preaccreditation standards, if offered, are appropriately related to the agency's accreditation standards and do not permit the institution or program to hold preaccreditation status for more than five years.

(b) If the agency only accredits programs and does not serve as an institutional accrediting agency for any of those programs, its accreditation standards must address the areas in paragraph (a)(1) of this section in terms of the type and level of the program rather than in terms of the institution.

(c) If none of the institutions an agency accredits participates in any Title IV, HEA program, or if the agency only accredits programs within institutions that are accredited by a

nationally recognized institutional accrediting agency, the agency is not required to have the accreditation standards described in paragraphs (a)(1)(viii) and (a)(1)(x) of this section.

(d) An agency that has established and applies the standards in paragraph (a) of this section may establish any additional accreditation standards it deems appropriate.

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(Authority: 20 U.S.C. 1099b)

### § 602.17 Application of standards in reaching an accrediting decision.

The agency must have effective mechanisms for evaluating an institution's or program's compliance with the agency's standards before reaching a decision to accredit or preaccredit the institution or program. The agency meets this requirement if the agency demonstrates that it—

(a) Evaluates whether an institution or program—

(1) Maintains clearly specified educational objectives that are consistent with its mission and appropriate in light of the degrees or certificates awarded;

(2) Is successful in achieving its stated objectives; and

(3) Maintains degree and certificate requirements that at least conform to commonly accepted standards;

(b) Requires the institution or program to prepare, following guidance provided by the agency, an in-depth self-study that includes the assessment of educational quality and the institution's or program's continuing efforts to improve educational quality;

(c) Conducts at least one on-site review of the institution or program during which it obtains sufficient information to determine if the institution or program complies with the agency's standards;

(d) Allows the institution or program the opportunity to respond in writing to the report of the on-site review;

(e) Conducts its own analysis of the self-study and supporting documentation furnished by the institution or program, the report of the on-site review, the institution's or program's response to the report, and any other appropriate information from other sources to determine whether the institution or program complies with the agency's standards; and

(f) Provides the institution or program with a detailed written report that assesses—

(1) The institution's or program's compliance with the agency's standards, including areas needing improvement; and

(2) The institution's or program's performance with respect to student achievement.

(Authority: 20 U.S.C. 1099b)

### § 602.18 Ensuring consistency in decision-making.

The agency must consistently apply and enforce its standards to ensure that the education or training offered by an institution or program, including any offered through distance education, is of sufficient quality to achieve its stated objective for the duration of any accreditation or preaccreditation period granted by the agency. The agency meets this requirement if the agency—

(a) Has effective controls against the inconsistent application of the agency's standards;

(b) Bases decisions regarding accreditation and preaccreditation on the agency's published standards; and

(c) Has a reasonable basis for determining that the information the agency relies on for making accrediting decisions is accurate.

(Authority: 20 U.S.C. 1099b)

### § 602.19 Monitoring and reevaluation of accredited institutions and programs.

(a) The agency must reevaluate, at regularly established intervals, the institutions or programs it has accredited or preaccredited.

(b) The agency must monitor institutions or programs throughout their accreditation or preaccreditation period to ensure that they remain in compliance with the agency's standards. This includes conducting special evaluations or site visits, as necessary.

(Authority: 20 U.S.C. 1099b)

### § 602.20 Enforcement of standards.

(a) If the agency's review of an institution or program under any standard indicates that the institution or program is not in compliance with that standard, the agency must—

(1) Immediately initiate adverse action against the institution or program; or

(2) Require the institution or program to take appropriate action to bring itself into compliance with the agency's standards within a time period that must not exceed—

(i) Twelve months, if the program, or the longest program offered by the institution, is less than one year in length;

(ii) Eighteen months, if the program, or the longest program offered by the institution, is at least one year, but less than two years, in length; or

(iii) Two years, if the program, or the longest program offered by the



institution, is at least two years in length.

(b) If the institution or program does not bring itself into compliance within the specified period, the agency must take immediate adverse action unless the agency, for good cause, extends the period for achieving compliance.

(Authority: 20 U.S.C. 1099b)

#### **§ 602.21 Review of standards.**

(a) The agency must maintain a systematic program of review that demonstrates that its standards are adequate to evaluate the quality of the education or training provided by the institutions and programs it accredits and relevant to the educational or training needs of students.

(b) The agency determines the specific procedures it follows in evaluating its standards, but the agency must ensure that its program of review—

- (1) Is comprehensive;
- (2) Occurs at regular, yet reasonable, intervals or on an ongoing basis;
- (3) Examines each of the agency's standards and the standards as a whole; and
- (4) Involves all of the agency's relevant constituencies in the review and affords them a meaningful opportunity to provide input into the review.

(c) If the agency determines, at any point during its systematic program of review, that it needs to make changes to its standards, the agency must initiate action within 12 months to make the changes and must complete that action within a reasonable period of time. Before finalizing any changes to its standards, the agency must—

- (1) Provide notice to all of the agency's relevant constituencies, and other parties who have made their interest known to the agency, of the changes the agency proposes to make;
- (2) Give the constituencies and other interested parties adequate opportunity to comment on the proposed changes; and
- (3) Take into account any comments on the proposed changes submitted timely by the relevant constituencies and by other interested parties.

(Authority: 20 U.S.C. 1099b)

#### **Required Operating Policies and Procedures**

#### **§ 602.22 Substantive change.**

(a) If the agency accredits institutions, it must maintain adequate substantive change policies that ensure that any substantive change to the educational mission, program, or programs of an institution after the agency has accredited or preaccredited the

institution does not adversely affect the capacity of the institution to continue to meet the agency's standards. The agency meets this requirement if—

(1) The agency requires the institution to obtain the agency's approval of the substantive change before the agency includes the change in the scope of accreditation or preaccreditation it previously granted to the institution; and

(2) The agency's definition of substantive change includes at least the following types of change:

- (i) Any change in the established mission or objectives of the institution.
- (ii) Any change in the legal status, form of control, or ownership of the institution.
- (iii) The addition of courses or programs that represent a significant departure, in either content or method of delivery, from those that were offered when the agency last evaluated the institution.

(iv) The addition of courses or programs at a degree or credential level above that which is included in the institution's current accreditation or preaccreditation.

(v) A change from clock hours to credit hours.

(vi) A substantial increase in the number of clock or credit hours awarded for successful completion of a program.

(vii) The establishment of an additional location geographically apart from the main campus at which the institution offers at least 50 percent of an educational program.

(b) The agency may determine the procedures it uses to grant prior approval of the substantive change. Except as provided in paragraph (c) of this section, these may, but need not, require a visit by the agency.

(c) If the agency's accreditation of an institution enables the institution to seek eligibility to participate in Title IV, HEA programs, the agency's procedures for the approval of an additional location described in paragraph (a)(2)(vii) of this section must determine if the institution has the fiscal and administrative capacity to operate the additional location. In addition, the agency's procedures must include—

- (1) A visit, within six months, to each additional location the institution establishes, if the institution—
  - (i) Has a total of three or fewer additional locations;
  - (ii) Has not demonstrated, to the agency's satisfaction, that it has a proven record of effective educational oversight of additional locations; or
  - (iii) Has been placed on warning, probation, or show cause by the agency

or is subject to some limitation by the agency on its accreditation or preaccreditation status;

(2) An effective mechanism for conducting, at reasonable intervals, visits to additional locations of institutions that operate more than three additional locations; and

(3) An effective mechanism, which may, at the agency's discretion, include visits to additional locations, for ensuring that accredited and preaccredited institutions that experience rapid growth in the number of additional locations maintain educational quality.

(d) The purpose of the visits described in paragraph (c) of this section is to verify that the additional location has the personnel, facilities, and resources it claimed to have in its application to the agency for approval of the additional location.

(Authority: 20 U.S.C. 1099b)

#### **§ 602.23 Operating procedures all agencies must have.**

(a) The agency must maintain and make available to the public, upon request, written materials describing—

- (1) Each type of accreditation and preaccreditation it grants;
- (2) The procedures that institutions or programs must follow in applying for accreditation or preaccreditation;
- (3) The standards and procedures it uses to determine whether to grant, reaffirm, reinstate, restrict, deny, revoke, terminate, or take any other action related to each type of accreditation and preaccreditation that the agency grants;
- (4) The institutions and programs that the agency currently accredits or preaccredits and, for each institution and program, the year the agency will next review or reconsider it for accreditation or preaccreditation; and
- (5) The names, academic and professional qualifications, and relevant employment and organizational affiliations of—

(i) The members of the agency's policy and decision-making bodies; and

(ii) The agency's principal administrative staff.

(b) In providing public notice that an institution or program subject to its jurisdiction is being considered for accreditation or preaccreditation, the agency must provide an opportunity for third-party comment concerning the institution's or program's qualifications for accreditation or preaccreditation. At the agency's discretion, third-party comment may be received either in writing or at a public hearing, or both.

(c) The accrediting agency must—

- (1) Review in a timely, fair, and equitable manner any complaint it

receives against an accredited institution or program that is related to the agency's standards or procedures;

(2) Take follow-up action, as necessary, including enforcement action, if necessary, based on the results of its review; and

(3) Review in a timely, fair, and equitable manner, and apply unbiased judgment to, any complaints against itself and take follow-up action, as appropriate, based on the results of its review.

(d) If an institution or program elects to make a public disclosure of its accreditation or preaccreditation status, the agency must ensure that the institution or program discloses that status accurately, including the specific academic or instructional programs covered by that status and the name, address, and telephone number of the agency.

(e) The accrediting agency must provide for the public correction of incorrect or misleading information an accredited or preaccredited institution or program releases about—

(1) The accreditation or preaccreditation status of the institution or program;

(2) The contents of reports of on-site reviews; and

(3) The agency's accrediting or preaccrediting actions with respect to the institution or program.

(f) The agency may establish any additional operating procedures it deems appropriate. At the agency's discretion, these may include unannounced inspections.

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(Authority: 20 U.S.C. 1099b)

#### **§ 602.24 Additional procedures certain institutional accreditors must have.**

If the agency is an institutional accrediting agency and its accreditation or preaccreditation enables those institutions to obtain eligibility to participate in Title IV, HEA programs, the agency must demonstrate that it has established and uses all of the following procedures:

(a) *Branch campus.* (1) The agency must require the institution to notify the agency if it plans to establish a branch campus and to submit a business plan for the branch campus that describes—

(i) The educational program to be offered at the branch campus;

(ii) The projected revenues and expenditures and cash flow at the branch campus; and

(iii) The operation, management, and physical resources at the branch campus.

(2) The agency may extend accreditation to the branch campus only after it evaluates the business plan and takes whatever other actions it deems necessary to determine that the branch campus has sufficient educational, financial, operational, management, and physical resources to meet the agency's standards.

(3) The agency must undertake a site visit to the branch campus as soon as practicable, but no later than six months after the establishment of that campus.

(b) *Change in ownership.* The agency must undertake a site visit to an institution that has undergone a change of ownership that resulted in a change of control as soon as practicable, but no later than six months after the change of ownership.

(c) *Teach-out agreements.* (1) The agency must require an institution it accredits or preaccredits that enters into a teach-out agreement with another institution to submit that teach-out agreement to the agency for approval.

(2) The agency may approve the teach-out agreement only if the agreement is between institutions that are accredited or preaccredited by a nationally recognized accrediting agency, is consistent with applicable standards and regulations, and provides for the equitable treatment of students by ensuring that—

(i) The teach-out institution has the necessary experience, resources, and support services to provide an educational program that is of acceptable quality and reasonably similar in content, structure, and scheduling to that provided by the closed institution; and

(ii) The teach-out institution demonstrates that it can provide students access to the program and services without requiring them to move or travel substantial distances.

(3) If an institution the agency accredits or preaccredits closes, the agency must work with the Department and the appropriate State agency, to the extent feasible, to ensure that students are given reasonable opportunities to complete their education without additional charge.

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(Authority: 20 U.S.C. 1099b)

#### **§ 602.25 Due process.**

The agency must demonstrate that the procedures it uses throughout the accrediting process satisfy due process. The agency meets this requirement if the agency does the following:

(a) The agency uses procedures that afford an institution or program a reasonable period of time to comply

with the agency's requests for information and documents.

(b) The agency notifies the institution or program in writing of any adverse accrediting action or an action to place the institution or program on probation or show cause. The notice describes the basis for the action.

(c) The agency permits the institution or program the opportunity to appeal an adverse action and the right to be represented by counsel during that appeal. If the agency allows institutions or programs the right to appeal other types of actions, the agency has the discretion to limit the appeal to a written appeal.

(d) The agency notifies the institution or program in writing of the result of its appeal and the basis for that result.

(Authority: 20 U.S.C. 1099b)

#### **§ 602.26 Notification of accrediting decisions.**

The agency must demonstrate that it has established and follows written procedures requiring it to provide written notice of its accrediting decisions to the Secretary, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and the public. The agency meets this requirement if the agency, following its written procedures—

(a) Provides written notice of the following types of decisions to the Secretary, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and the public no later than 30 days after it makes the decision:

(1) A decision to award initial accreditation or preaccreditation to an institution or program.

(2) A decision to renew an institution's or program's accreditation or preaccreditation;

(b) Provides written notice of the following types of decisions to the Secretary, the appropriate State licensing or authorizing agency, and the appropriate accrediting agencies at the same time it notifies the institution or program of the decision, but no later than 30 days after it reaches the decision:

(1) A final decision to place an institution or program on probation or an equivalent status.

(2) A final decision to deny, withdraw, suspend, revoke, or terminate the accreditation or preaccreditation of an institution or program;

(c) Provides written notice to the public of the decisions listed in paragraphs (b)(1) and (b)(2) of this section within 24 hours of its notice to the institution or program;

(d) For any decision listed in paragraph (b)(2) of this section, makes available to the Secretary, the appropriate State licensing or authorizing agency, and the public upon request, no later than 60 days after the decision, a brief statement summarizing the reasons for the agency's decision and the comments, if any, that the affected institution or program may wish to make with regard to that decision; and

(e) Notifies the Secretary, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and, upon request, the public if an accredited or preaccredited institution or program—

(1) Decides to withdraw voluntarily from accreditation or preaccreditation, within 30 days of receiving notification from the institution or program that it is withdrawing voluntarily from accreditation or preaccreditation; or

(2) Lets its accreditation or preaccreditation lapse, within 30 days of the date on which accreditation or preaccreditation lapses.

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(Authority: 20 U.S.C. 1099b)

**§ 602.27 Other information an agency must provide the Department.**

The agency must submit to the Department—

(a) A copy of any annual report it prepares;

(b) A copy, updated annually, of its directory of accredited and preaccredited institutions and programs;

(c) A summary of the agency's major accrediting activities during the previous year (an annual data summary), if requested by the Secretary to carry out the Secretary's responsibilities related to this part;

(d) Any proposed change in the agency's policies, procedures, or accreditation or preaccreditation standards that might alter it—

(1) Scope of recognition; or

(2) Compliance with the criteria for recognition;

(e) The name of any institution or program it accredits that the agency has reason to believe is failing to meet its Title IV, HEA program responsibilities or is engaged in fraud or abuse, along with the agency's reasons for concern about the institution or program; and

(f) If the Secretary requests, information that may bear upon an accredited or preaccredited institution's compliance with its Title IV, HEA program responsibilities, including the eligibility of the institution or program to participate in Title IV, HEA programs. The Secretary may ask for this

information to assist the Department in resolving problems with the institution's participation in the Title IV, HEA programs.

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(Authority: 20 U.S.C. 1099b)

**§ 602.28 Regard for decisions of States and other accrediting agencies.**

(a) If the agency is an institutional accrediting agency, it may not accredit or preaccredit institutions that lack legal authorization under applicable State law to provide a program of education beyond the secondary level.

(b) Except as provided in paragraph (c) of this section, the agency may not grant initial or renewed accreditation or preaccreditation to an institution, or a program offered by an institution, if the agency knows, or has reasonable cause to know, that the institution is the subject of—

(1) A pending or final action brought by a State agency to suspend, revoke, withdraw, or terminate the institution's legal authority to provide postsecondary education in the State;

(2) A decision by a recognized agency to deny accreditation or preaccreditation;

(3) A pending or final action brought by a recognized accrediting agency to suspend, revoke, withdraw, or terminate the institution's accreditation or preaccreditation; or

(4) Probation or an equivalent status imposed by a recognized agency.

(c) The agency may grant accreditation or preaccreditation to an institution or program described in paragraph (b) of this section only if it provides to the Secretary, within 30 days of its action, a thorough and reasonable explanation, consistent with its standards, why the action of the other body does not preclude the agency's grant of accreditation or preaccreditation.

(d) If the agency learns that an institution it accredits or preaccredits, or an institution that offers a program it accredits or preaccredits, is the subject of an adverse action by another recognized accrediting agency or has been placed on probation or an equivalent status by another recognized agency, the agency must promptly review its accreditation or preaccreditation of the institution or program to determine if it should also take adverse action or place the institution or program on probation or show cause.

(e) The agency must, upon request, share with other appropriate recognized accrediting agencies and recognized State approval agencies information

about the accreditation or preaccreditation status of an institution or program and any adverse actions it has taken against an accredited or preaccredited institution or program.

(Approved by the Office of Management and Budget under control number 1845-0003)

(Authority: 20 U.S.C. 1099b)

**Subpart C—The Recognition Process**

**Application and Review by Department Staff**

**§ 602.30 How does an agency apply for recognition?**

(a) An accrediting agency seeking initial or continued recognition must submit a written application to the Secretary. The application must consist of—

(1) A statement of the agency's requested scope of recognition;

(2) Evidence that the agency complies with the criteria for recognition listed in subpart B of this part; and

(3) Supporting documentation.

(b) By submitting an application for recognition, the agency authorizes Department staff to observe its site visits and decision meetings and to gain access to agency records, personnel, and facilities on an announced or unannounced basis.

(c) The Secretary does not make available to the public any confidential agency materials a Department employee reviews during the evaluation of either the agency's application for recognition or the agency's compliance with the criteria for recognition.

(Approved by the Office of Management and Budget under control number 1845-0003)

(Authority: 20 U.S.C. 1099b)

**§ 602.31 How does Department staff review an agency's application?**

(a) Upon receipt of an agency's application for either initial or continued recognition, Department staff—

(1) Establishes a schedule for the review of the agency by Department staff, the National Advisory Committee on Institutional Quality and Integrity, and the Secretary;

(2) Publishes a notice of the agency's application in the **Federal Register**, inviting the public to comment on the agency's compliance with the criteria for recognition and establishing a deadline for receipt of public comment; and

(3) Provides State licensing or authorizing agencies, all currently recognized accrediting agencies, and other appropriate organizations with copies of the **Federal Register** notice.

(b) Department staff analyzes the agency's application to determine

whether the agency satisfies the criteria for recognition, taking into account all available relevant information concerning the compliance of the agency with those criteria and any deficiencies in the agency's performance with respect to the criteria. The analysis includes—

(1) Site visits, on an announced or unannounced basis, to the agency and, at the Secretary's discretion, to some of the institutions or programs it accredits or preaccredits;

(2) Review of the public comments and other third-party information the Department staff receives by the established deadline, as well as any other information Department staff assembles for purposes of evaluating the agency under this part; and

(3) Review of complaints or legal actions involving the agency.

(c) Department staff's evaluation may also include a review of information directly related to institutions or programs accredited or preaccredited by the agency relative to their compliance with the agency's standards, the effectiveness of the standards, and the agency's application of those standards.

(d) If, at any point in its evaluation of an agency seeking initial recognition, Department staff determines that the agency fails to demonstrate substantial compliance with the basic eligibility requirements in §§ 602.10 through 602.13, the staff—

(1) Returns the agency's application and provides the agency with an explanation of the deficiencies that caused staff to take that action; and

(2) Recommends that the agency withdraw its application and reapply when the agency can demonstrate compliance.

(e) Except with respect to an application that is withdrawn under paragraph (d) of this section, when Department staff completes its evaluation of the agency, the staff—

(1) Prepares a written analysis of the agency, which includes a recognition recommendation;

(2) Sends the analysis and all supporting documentation, including all third-party comments the Department received by the established deadline, to the agency no later than 45 days before the Advisory Committee meeting; and

(3) Invites the agency to provide a written response to the staff analysis and third-party comments, specifying a deadline for the response that is at least two weeks before the Advisory Committee meeting.

(f) If Department staff fails to provide the agency with the materials described in paragraph (e)(2) of this section at least 45 days before the Advisory

Committee meeting, the agency may request that the Advisory Committee defer acting on the application at that meeting. If Department staff's failure to send the materials at least 45 days before the Advisory Committee meeting is due to the failure of the agency to submit reports or other information the Secretary requested by the deadline the Secretary established, the agency forfeits its right to request a deferral.

(g) Department staff reviews any response to the staff analysis that the agency submits. If necessary, Department staff prepares an addendum to the staff analysis and provides the agency with a copy.

(h) Before the Advisory Committee meeting, Department staff provides the Advisory Committee with the following information:

(1) The agency's application for recognition and supporting documentation.

(2) The Department staff analysis of the agency.

(3) Any written third-party comments the Department received about the agency on or before the established deadline.

(4) Any agency response to either the Department staff analysis or third-party comments.

(5) Any addendum to the Department staff analysis.

(6) Any other information Department staff relied on in developing its analysis.

(i) At least 30 days before the Advisory Committee meeting, the Department publishes a notice of the meeting in the **Federal Register** inviting interested parties, including those who submitted third-party comments concerning the agency's compliance with the criteria for recognition, to make oral presentations before the Advisory Committee.

(Authority: 20 U.S.C. 1099b)

Review by the National Advisory Committee on Institutional Quality and Integrity

**§ 602.32 What is the role of the Advisory Committee and the senior Department official in the review of an agency's application?**

(a) The Advisory Committee considers an agency's application for recognition at a public meeting and invites Department staff, the agency, and other interested parties to make oral presentations at the meeting. A transcript is made of each Advisory Committee meeting.

(b) When it concludes its review, the Advisory Committee recommends that the Secretary either approve or deny recognition or that the Secretary defer a

decision on the agency's application for recognition.

(1)(i) The Advisory Committee recommends approval of recognition if the agency complies with the criteria for recognition listed in subpart B of this part and if the agency is effective in its performance with respect to those criteria.

(ii) If the Advisory Committee recommends approval, the Advisory Committee also recommends a recognition period and a scope of recognition.

(iii) If the recommended scope or period of recognition is less than that requested by the agency, the Advisory Committee explains its reasons for recommending the lesser scope or recognition period.

(2)(i) If the agency fails to comply with the criteria for recognition in subpart B of this part, or if the agency is not effective in its performance with respect to those criteria, the Advisory Committee recommends denial of recognition, unless the Advisory Committee concludes that a deferral under paragraph (b)(3) of this section is warranted.

(ii) If the Advisory Committee recommends denial, the Advisory Committee specifies the reasons for its recommendation, including all criteria the agency fails to meet and all areas in which the agency fails to perform effectively.

(3)(i) The Advisory Committee may recommend deferral of a decision on recognition if it concludes that the agency's deficiencies do not warrant immediate loss of recognition and if it concludes that the agency will demonstrate or achieve compliance with the criteria for recognition and effective performance with respect to those criteria before the expiration of the deferral period.

(ii) In its deferral recommendation, the Advisory Committee states the bases for its conclusions, specifies any criteria for recognition the agency fails to meet, and identifies any areas in which the agency fails to perform effectively with respect to the criteria.

(iii) The Advisory Committee also recommends a deferral period, which may not exceed 12 months, either as a single deferral period or in combination with any expiring deferral period in which similar deficiencies in compliance or performance were cited by the Secretary.

(c) At the conclusion of its meeting, the Advisory Committee forwards its recommendations to the Secretary through the senior Department official.

(d) For any Advisory Committee recommendation not appealed under

§ 602.33, the senior Department official includes with the Advisory Committee materials forwarded to the Secretary a memorandum containing the senior Department official's recommendations regarding the actions proposed by the Advisory Committee.

(Authority: 20 U.S.C. 1099b and 1145)

**§ 602.33 How may an agency appeal a recommendation of the Advisory Committee?**

(a) Either the agency or the senior Department official may appeal the Advisory Committee's recommendation. If a party wishes to appeal, that party must—

(1) Notify the Secretary and the other party in writing of its intent to appeal the recommendation no later than 10 days after the Advisory Committee meeting;

(2) Submit its appeal in writing to the Secretary no later than 30 days after the Advisory Committee meeting; and

(3) Provide the other party with a copy of the appeal at the same time it submits the appeal to the Secretary.

(b) The non-appealing party may file a written response to the appeal. If that party wishes to do so, it must—

(1) Submit its response to the Secretary no later than 30 days after receiving its copy of the appeal; and

(2) Provide the appealing party with a copy of its response at the same time it submits its response to the Secretary.

(c) Neither the agency nor the senior Department official may include any new evidence in its submission; i.e., evidence it did not previously submit to the Advisory Committee.

(Authority: 20 U.S.C. 1099b and 1145)  
Review and Decision by the Secretary

**§ 602.34 What does the Secretary consider when making a recognition decision?**

The Secretary makes the decision regarding recognition of an agency based on the entire record of the agency's application, including the following:

(a) The Advisory Committee's recommendation.

(b) The senior Department official's recommendation, if any.

(c) The agency's application and supporting documentation.

(d) The Department staff analysis of the agency.

(e) All written third-party comments forwarded by Department staff to the Advisory Committee for consideration at the meeting.

(f) Any agency response to the Department staff analysis and third-party comments.

(g) Any addendum to the Department staff analysis.

(h) All oral presentations at the Advisory Committee meeting.

(i) Any materials submitted by the parties, within the established timeframes, in an appeal taken in accordance with § 602.33.

(Authority: 20 U.S.C. 1099b)

**§ 602.35 What information does the Secretary's recognition decision include?**

(a) The Secretary notifies the agency in writing of the Secretary's decision regarding the agency's application for recognition.

(b) The Secretary either approves or denies recognition or defers a decision on the agency's application for recognition.

(1)(i) The Secretary approves recognition if the agency complies with the criteria for recognition listed in subpart B of this part and if the agency is effective in its performance with respect to those criteria.

(ii) If the Secretary approves recognition, the Secretary's recognition decision defines the scope of recognition and the recognition period.

(iii) If the scope or period of recognition is less than that requested by the agency, the Secretary explains the reasons for approving a lesser scope or recognition period.

(2)(i) If the agency fails to comply with the criteria for recognition in subpart B of this part, or if the agency is not effective in its performance with respect to those criteria, the Secretary denies recognition, unless the Secretary concludes that a deferral under paragraph (b)(3) of this section is warranted.

(ii) If the Secretary denies recognition, the Secretary specifies the reasons for this decision, including all criteria the agency fails to meet and all areas in which the agency fails to perform effectively.

(3)(i) The Secretary may defer a decision on recognition if the Secretary concludes that the agency's deficiencies do not warrant immediate loss of recognition and if the Secretary concludes that the agency will demonstrate or achieve compliance with the criteria for recognition and effective performance with respect to those criteria before the expiration of the deferral period.

(ii) In the deferral decision, the Secretary states the bases for the Secretary's conclusions, specifies any criteria for recognition the agency fails to meet, and identifies any areas in which the agency fails to perform effectively with respect to the criteria.

(iii) The Secretary also establishes a deferral period, which begins on the date of the Secretary's decision.

(iv) The deferral period may not exceed 12 months, either as a single deferral period or in combination with any expiring deferral period in which similar deficiencies in compliance or performance were cited by the Secretary, except that the Secretary may grant an extension of an expiring deferral period at the request of the agency for good cause shown.

(c) The recognition period may not exceed five years.

(d) If the Secretary does not reach a final decision to approve or deny an agency's application for continued recognition before the expiration of its recognition period, the Secretary automatically extends the recognition period until the final decision is reached.

(Authority: 20 U.S.C. 1099b)

**§ 602.36 May an agency appeal the Secretary's final recognition decision?**

An agency may appeal the Secretary's decision under this part in the Federal courts as a final decision in accordance with applicable Federal law.

(Authority: 20 U.S.C. 1099b)

**Subpart D—Limitation, Suspension, or Termination of Recognition Limitation, Suspension, and Termination Procedures**

**§ 602.40 How may the Secretary limit, suspend, or terminate an agency's recognition?**

(a) If the Secretary determines, after notice and an opportunity for a hearing, that a recognized agency does not comply with the criteria for recognition in subpart B of this part or that the agency is not effective in its performance with respect to those criteria, the Secretary—

(1) Limits, suspends, or terminates the agency's recognition; or

(2) Requires the agency to take appropriate action to bring itself into compliance with the criteria and achieve effectiveness within a timeframe that may not exceed 12 months.

(b) If, at the conclusion of the timeframe specified in paragraph (a)(2) of this section, the Secretary determines, after notice and an opportunity for a hearing, that the agency has failed to bring itself into compliance or has failed to achieve effectiveness, the Secretary limits, suspends, or terminates recognition, unless the Secretary extends the timeframe, on request by the agency for good cause shown.

(Authority: 20 U.S.C. 1099b).

**§ 602.41 What are the notice procedures?**

(a) Department staff initiates an action to limit, suspend, or terminate an agency's recognition by notifying the agency in writing of the Secretary's intent to limit, suspend, or terminate recognition. The notice—

(1) Describes the specific action the Secretary seeks to take against the agency and the reasons for that action, including the criteria with which the agency has failed to comply;

(2) Specifies the effective date of the action; and

(3) Informs the agency of its right to respond to the notice and request a hearing.

(b) Department staff may send the notice described in paragraph (a) of this section at any time the staff concludes that the agency fails to comply with the criteria for recognition in subpart B of this part or is not effective in its performance with respect to those criteria.

(Authority: 20 U.S.C. 1099b)

**§ 602.42 What are the response and hearing procedures?**

(a) If the agency wishes either to respond to the notice or request a hearing, or both, it must do so in writing no later than 30 days after it receives the notice of the Secretary's intent to limit, suspend, or terminate recognition.

(1) The agency's submission must identify the issues and facts in dispute and the agency's position on them.

(2) If neither a response nor a request for a hearing is filed by the deadline, the notice of intent becomes a final decision by the Secretary.

(b)(1) After receiving the agency's response and hearing request, if any, the Secretary chooses a subcommittee composed of five members of the Advisory Committee to adjudicate the matter and notifies the agency of the subcommittee's membership.

(2) The agency may challenge membership of the subcommittee on grounds of conflict of interest on the part of one or more members and, if the agency's challenge is successful, the Secretary will replace the member or members challenged.

(c) After the subcommittee has been selected, Department staff sends the members of the subcommittee copies of the notice to limit, suspend, or terminate recognition, along with the agency's response, if any.

(d)(1) If a hearing is requested, it is held in Washington, DC, at a date and time set by Department staff.

(2) A transcript is made of the hearing.

(3) Except as provided in paragraph (e) of this section, the subcommittee allows Department staff, the agency, and any interested party to make an oral or written presentation, which may include the introduction of written and oral evidence.

(e) On agreement by Department staff and the agency, the subcommittee review may be based solely on the written materials submitted.

(Authority: 20 U.S.C. 1099b)

**§ 602.43 How is a decision on limitation, suspension, or termination of recognition reached?**

(a) After consideration of the notice of intent to limit, suspend, or terminate recognition, the agency's response, if any, and all submissions and presentations made at the hearing, if any, the subcommittee issues a written opinion and sends it to the Secretary, with copies to the agency and the senior Department official. The opinion includes—

(1) Findings of fact, based on consideration of all the evidence, presentations, and submissions before the subcommittee;

(2) A recommendation as to whether a limitation, suspension, or termination of the agency's recognition is warranted; and

(3) The reasons supporting the subcommittee's recommendation.

(b) Unless the subcommittee's recommendation is appealed under § 602.44, the Secretary issues a final decision on whether to limit, suspend, or terminate the agency's recognition. The Secretary bases the decision on consideration of the full record before the subcommittee and the subcommittee's opinion.

(Authority: 20 U.S.C. 1099b)

**Appeal Rights and Procedures****§ 602.44 How may an agency appeal the subcommittee's recommendation?**

(a) Either the agency or the senior Department official may appeal the subcommittee's recommendation. If a party wishes to appeal, that party must—

(1) Notify the Secretary and the other party in writing of its intent to appeal the recommendation no later than 10 days after receipt of the recommendation;

(2) Submit its appeal to the Secretary in writing no later than 30 days after receipt of the recommendation; and

(3) Provide the other party with a copy of the appeal at the same time it submits the appeal to the Secretary.

(b) The non-appealing party may file a written response to the appeal. If that party wishes to do so, it must—

(1) Submit its response to the Secretary no later than 30 days after receiving its copy of the appeal; and

(2) Provide the appealing party with a copy of its response at the same time it submits its response to the Secretary.

(c) Neither the agency nor the senior Department official may include any new evidence in its submission, i.e., evidence it did not previously submit to the subcommittee.

(d) If the subcommittee's recommendation is appealed, the Secretary renders a final decision after taking into account that recommendation and the parties' written submissions on appeal, as well as the entire record before the subcommittee and the subcommittee's opinion.

(Authority: 20 U.S.C. 1099b)

**§ 602.45 May an agency appeal the Secretary's final decision to limit, suspend, or terminate its recognition?**

An agency may appeal the Secretary's final decision limiting, suspending, or terminating its recognition to the Federal courts as a final decision in accordance with applicable Federal law.

(Authority: 20 U.S.C. 1099b)

**Subpart E—Department Responsibilities****§ 602.50 What information does the Department share with a recognized agency about its accredited institutions and programs?**

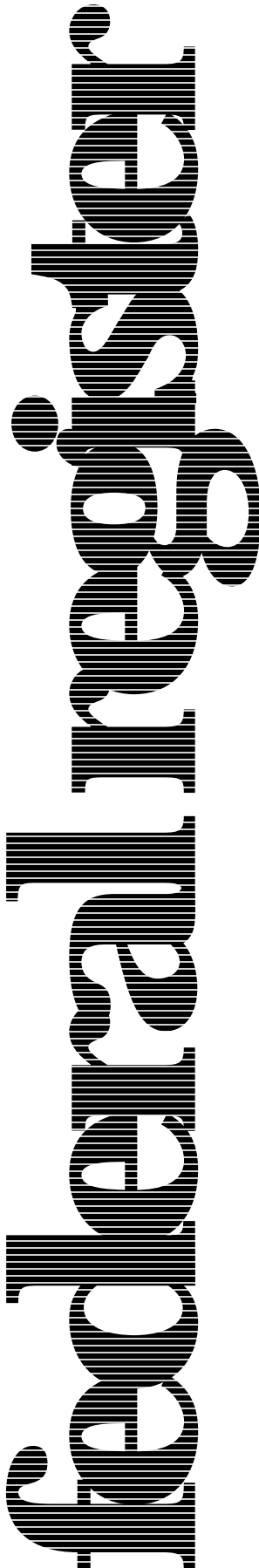
(a) If the Department takes an action against an institution or program accredited by the agency, it notifies the agency no later than 10 days after taking that action.

(b) If another Federal agency or a State agency notifies the Department that it has taken an action against an institution or program accredited by the agency, the Department notifies the agency as soon as possible but no later than 10 days after receiving the written notice from the other Government agency.

(Authority: 20 U.S.C. 1099b)

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Wednesday  
October 20, 1999

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## Part IV

# Office of Management and Budget

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Recommendations From the Metropolitan  
Area Standards Review Committee to the  
Office of Management and Budget  
Concerning Changes to the Standards for  
Defining Metropolitan Areas; Notice



## OFFICE OF MANAGEMENT AND BUDGET

### Recommendations From the Metropolitan Area Standards Review Committee to the Office of Management and Budget Concerning Changes to the Standards for Defining Metropolitan Areas

**AGENCY:** Executive Office of the President, Office of Management and Budget (OMB), Office of Information and Regulatory Affairs.

**ACTION:** Notice and request for comments.

**SUMMARY:** OMB requests comments on recommendations that it has received from the Metropolitan Area Standards Review Committee (MASRC) for changes to OMB's metropolitan area (MA) standards. MASRC's report and recommendations, which are published in their entirety in the Appendix, are the result of a comprehensive review of the MA concept and current (1990) standards that began earlier this decade. The review will culminate in publication prior to Census 2000 of standards for the first decade of the next century.

**DATES:** To ensure consideration during the final decision making process, written comments must be received no later than December 20, 1999.

**ADDRESSES:** Written comments on the recommendations should be submitted to James D. Fitzsimmons, U.S. Bureau of the Census, IPC-Population Division, Washington, DC 20233-8860; fax (301) 457-3034.

**Electronic Data Availability:** This **Federal Register** Notice is available electronically from the OMB home page: <<<http://www.whitehouse.gov/OMB/fedreg/index.html>>>. **Federal Register** Notices also are available electronically from the U.S. Government Printing Office web site: <<[http://www.access.gpo.gov/su\\_docs/aces/aces140.html](http://www.access.gpo.gov/su_docs/aces/aces140.html)>>.

**FOR FURTHER INFORMATION CONTACT:** James D. Fitzsimmons, Chair, Metropolitan Area Standards Review Committee, (301) 457-2419; or E-mail <<[pop.frquestion@ccmail.census.gov](mailto:pop.frquestion@ccmail.census.gov)>>.

#### SUPPLEMENTARY INFORMATION:

##### Outline of Notice

1. Background
2. Review Process
3. Summary of Comments Received in Response to the **Federal Register** Notice of December 21, 1998
4. Overview of MASRC Report
5. Issues for Comment

### Appendix—Report to the Office of Management and Budget on the Review of the Metropolitan Area Standards and Recommendations for Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century

- A. Formation of the Metropolitan Area Standards Review Committee
- B. Public Participation and Comment
- C. Review Process
- D. Principles Guiding Review and Development of Recommendations
- E. Issues Under Review
- F. Comparison of the Current Metropolitan Area Standards with the Recommended Core-Based Statistical Area Standards
- G. Recommended Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century
- H. Key Terms

#### 1. Background

The metropolitan area (MA) program has provided standard statistical area definitions at the metropolitan level for 50 years. In the 1940s, it became clear that the value of data produced at that level by Federal Government agencies would be greatly enhanced if agencies used a single set of geographic definitions for the Nation's metropolitan areas. The Office of Management and Budget's (OMB's) predecessor, the Bureau of the Budget, led the effort to develop what were then called "standard metropolitan areas" in time for their use in 1950 census reports. Since then, vast numbers of directly comparable MA data products have been made available to government, business, scholars, citizens' organizations, and others interested in studying various aspects of MAs.

The general concept of an MA is that of an area containing a large population nucleus and adjacent communities that have a high degree of integration with that nucleus. This general concept has remained essentially the same since MAs were first defined before the 1950 census. The purpose of MAs also is unchanged from when they were first defined: the classification provides a nationally consistent set of definitions for collecting, tabulating, and publishing Federal statistics for geographic areas. Stated differently, OMB establishes and maintains MAs solely for statistical purposes. *In reviewing and revising MAs, OMB does not take into account or attempt to anticipate any public or private sector nonstatistical uses that may be made of the definitions.*

The evolution of the standards for defining MAs was discussed in detail in OMB's **Federal Register** Notice of December 21, 1998, "Alternative Approaches to Defining Metropolitan and Nonmetropolitan Areas" (63 FR

70526-70561). Table 1 of the December Notice summarized the evolution of MA standards since 1950. (The December Notice is available on the OMB web site.)

#### 2. Review Process

The MA standards are reviewed and, if warranted, revised in the years preceding each decennial census. Periodic review of the MA standards is necessary to ensure their continued usefulness and relevance. The current review of the MA standards—the Metropolitan Area Standards Review Project (MASRP)—is the sixth such review; it has been especially thorough, reflecting as a first priority users' concerns with the conceptual and operational complexity of the standards that have evolved over the decades. Other key concerns behind the particularly thorough nature of MASRP's efforts have been: (1) whether modifications to the standards over the years have permitted them to stay abreast of changes in population distribution and activity patterns; (2) whether advances in computer applications permit consideration of new approaches to defining areas; and (3) whether there is a practicable way to capture a more complete range of U.S. settlement and activity patterns than the current MA standards capture.

Specific, major issues addressed by MASRP have included:

- Whether the Federal Government should define metropolitan and nonmetropolitan statistical areas;
- The geographic units—"building blocks"—that should be used in defining the statistical areas;
- The criteria that should be used to aggregate the building blocks in defining the statistical areas;
- Whether the statistical areas should account for all territory of the Nation;
- Whether there should be hierarchies or multiple sets of statistical areas in the classification;
- The kinds of entities that should receive official recognition in the classification;
- Whether the classification should reflect statistical rules only or allow a role for local opinion; and
- How frequently statistical areas should be updated.

This decade's review has included several Census Bureau research projects, open conferences held in November 1995 and January 1999, a congressional hearing in July 1997, presentations at professional and academic conferences, and meetings with Federal, State, and local officials.

In fall 1998, OMB chartered the Metropolitan Area Standards Review

Committee (MASRC) and charged it with the tasks of examining the current MA standards and providing recommendations for possible changes to those standards. Agencies represented on MASRC include the Census Bureau (Chair), Bureau of Economic Analysis, Bureau of Labor Statistics, Bureau of Transportation Statistics, Economic Research Service (Agriculture), National Center for Health Statistics, and *ex officio*, OMB. The Census Bureau has provided research support to MASRC. MASRC's report summarizes the research and review process that led to the committee's recommendations (see Appendix, Section C).

This Notice is the second of three Notices related to the review of the standards. The first was published by OMB in the **Federal Register** of December 21, 1998. A summary of comments received in response to that Notice is provided in Section 3 below. OMB expects to publish the final standards in the third Notice prior to census day (April 1) 2000.

Ongoing research projects, although not intended to provide additional information for formulating final standards for the next decade, will further understanding of patterns of settlement and activity of the Nation's population and provide information for use in future reviews of the standards. Research will continue into aspects of all of the alternative approaches (and variations thereof) presented in the December 1998 **Federal Register** Notice. For example, Census Bureau staff are investigating the feasibility of developing a census tract-level classification to identify settlement and land use categories along an urban-rural continuum. The Census Bureau also has a project to conduct additional research on the comparative density approach outlined in the December 1998 **Federal Register** Notice and is continuing research on potential uses of directional commuting statistics in defining statistical areas. Outcomes of this work may be featured in pilot projects of the Census Bureau or other agencies during the next decade.

### 3. Summary of Comments Received in Response to the Federal Register Notice of December 21, 1998

The December 21, 1998 **Federal Register** Notice (63 FR 70526-70561) called for comments on: (1) the suitability of the current standards, (2) the principles that should govern any proposed revisions to the standards, (3) reactions to the four approaches outlined in the Notice, and (4) proposals for alternative ways to define

metropolitan and nonmetropolitan areas. The December Notice also called for comments on the following questions: (1) What geographic unit should be used as the "building block" for defining areas for statistical purposes? (2) What criteria should be used to aggregate the geographic building blocks into statistical areas? (3) What criteria should be used to define a set of statistical areas of different types that together classify all the territory of the Nation?

A total of 40 comments were received from individuals (ten), municipalities (eight), State government agencies (seven), nongovernmental organizations (seven), Federal agencies (four), chambers of commerce (two), and regional government organizations (two).

Among commenters, the largest number (ten) preferred the commuting-based, county-level approach (presented in Part IV, Section A of the December Notice). Four commenters preferred the commuting-based, census tract-level approach (Part IV, Section B). The directional commuting, census tract-level approach (Part IV, Section C) was the choice of one commenter, and two stated a preference for the comparative density, county-level approach (Part IV, Section D). Two commenters preferred adoption of both the commuting-based, county-level and the commuting-based, census tract-level approaches. Twenty-one commenters did not indicate a preference for any of the four alternative approaches presented. Comment letters generally emphasized specific issues rather than overall approaches for classifying areas.

The issue of what geographic entity to use as a building block for defining metropolitan and nonmetropolitan areas drew the largest number of comments. Thirty-five of the 40 commenters specifically indicated building block preferences. Of these, 25 preferred continued use of counties, five preferred use of census tracts, and two preferred use of minor civil divisions (MCDs). Three commenters indicated a preference for dual classifications—one using counties as building blocks and the other using census tracts. Three commenters favored continued use of MCDs as building blocks for statistical areas in New England.

Of the 40 commenters, 24 remarked on the kind of measure to be used in aggregating entities to define metropolitan and nonmetropolitan areas. Twenty-one favored use of commuting (journey-to-work) data as the primary means of determining the geographic extent of metropolitan and nonmetropolitan areas. A few

commenters, however, expressed concern that commuting data do not describe all patterns of activity and, therefore, cannot portray all social and economic linkages between entities. With respect to specific commuting criteria to be used in qualifying entities for inclusion within metropolitan and nonmetropolitan areas, one commenter suggested a 30 to 35 percent minimum commuting requirement; another suggested a 25 percent minimum commuting requirement. No other comments were received regarding specific commuting thresholds.

Central city identification received little attention. Of the four commenters who did respond on this issue, three favored continued identification of central cities; one favored discontinuing this practice. Four comments were received in response to the related issue of identifying urban, suburban, rural, and other settlement categories as part of the standards. Three commenters favored identification of such categories as part of the standards; one commented negatively, noting that identification of these categories is a separate issue that should be addressed in a classification system that focuses on settlement form (*i.e.*, what can be seen on the land) and not functional ties (*i.e.*, interactions of people and activities among places).

Fifteen comments were received on whether and how a statistical area classification should account for all territory in the United States. Twelve favored development of a classification that accounted for all of the territory of the Nation, but they varied considerably on how to do so. Three commenters endorsed defining MAs only.

The role of local opinion in defining metropolitan and nonmetropolitan areas drew two comments: one favored a limited use of local opinion, such as in naming areas; the other noted that local opinion should be solicited in a timely manner.

Although some commenters did offer alternative proposals for geographic entities to be used as building blocks, means of measuring the extent of areas, and ways of identifying settlement categories within the classification system, no additional proposals for alternative approaches to defining metropolitan and nonmetropolitan areas were received.

### 4. Overview of MASRC Report

This **Federal Register** Notice makes available for comment MASRC's recommendations to OMB for how the current MA standards should be revised. These recommendations are presented in their entirety in MASRC's "Report to the Office of Management

and Budget on the Review of the Metropolitan Area Standards and Recommendations for Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century," provided in the Appendix to this Notice. Section G of the Appendix presents for public comment the specific standards recommended by MASRC for adoption by OMB. This overview summarizes MASRC's recommendations to OMB, with particular attention to recommendations that represent noteworthy conclusions and changes to the current standards or pertain to issues of special importance to users and providers of data for metropolitan and nonmetropolitan areas.

MASRC has recommended a Core-Based Statistical Area (CBSA) Classification to replace the current MA classification. The cores (*i.e.*, the densely settled concentrations of population) for this classification would be Census Bureau-defined urbanized areas and smaller densely settled "settlement clusters" identified in Census 2000. CBSAs would be defined around these cores. This CBSA Classification has three types of areas based on the *total* population of all cores in the CBSA: (1) Megapolitan Areas defined around cores of at least 1,000,000 population; (2) Macropolitan Areas defined around cores of 50,000 to 999,999 population; and (3) Micropolitan Areas defined around cores of 10,000 to 49,999 population. The identification of Micropolitan Areas extends concepts underlying the core-based approach to smaller population centers previously included in a "nonmetropolitan residual."

MASRC has recommended use of counties and equivalent entities as the building blocks for statistical areas throughout the United States and Puerto Rico, including the use of counties as the primary building blocks for statistical areas in New England. This recommendation does not preclude the potential adoption of a sub-county entity as the building block for statistical areas in the future. MASRC also has recommended that MCDs be used as building blocks for an alternative set of statistical areas for the New England States only.

MASRC has recommended adoption of a single commuting threshold of 25 percent to establish qualifying linkages between outlying counties and counties containing CBSA cores. In addition, MASRC recommends eliminating the use of measures of settlement structure, such as population density and percent of population that is urban, in conjunction with commuting when

considering whether outlying counties qualify for inclusion. This change reduces the conceptual and operational complexity of the standards but may affect the geographic extent of some existing areas defined according to the current MA standards.

### 5. Issues for Comment

With this Notice, OMB requests comments on the recommendations it has received from MASRC concerning revisions to the current standards for defining MAs. The standards recommended to OMB for adoption are presented in Section G of MASRC's report. The complete report is included in the Appendix to this Notice to provide information on the review process and a context for MASRC's recommendations. In particular, Section E of the report provides a discussion of the recommendations on the various issues considered by MASRC. Section F presents a comparison of the current MA standards with the recommended CBSA Classification. OMB would appreciate receiving views and comments on any aspects of the recommended standards.

**John T. Spotila,**

*Administrator, Office of Information and Regulatory Affairs.*

### **Appendix—Report to the Office of Management and Budget on the Review of the Metropolitan Area Standards and Recommendations for Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century**

*Prepared by the Metropolitan Area Standards Review Committee*

[Transmittal Memorandum]

September 20, 1999

Memorandum for Katherine K. Wallman,  
Chief Statistician, Office of Management  
and Budget

From: Metropolitan Area Standards Review  
Committee

Subject: Transmittal of Report and  
Recommendations for Standards for  
Defining Core-Based Statistical Areas

We are pleased to transmit to you the attached report presenting this committee's recommendations for modifying the Office of Management and Budget's (OMB's) standards for defining metropolitan areas. The recommendations are outlined and discussed in Section E of the report. They represent our best technical and professional advice for how the standards could better account for and describe changes in settlement and activity patterns throughout the United States and Puerto Rico yet still meet the data reporting needs and requirements of Federal agencies and the public.

Our recommendations for a Core-Based Statistical Area Classification are the product of a ten-year review process. During that time, a research program was designed and implemented to determine whether the current (1990) standards were in need of revision as well as to identify and evaluate alternative approaches to defining metropolitan and nonmetropolitan areas. Section A of our report discusses the formation of the Metropolitan Area Standards Review Committee (MASRC) and outlines the tasks assigned by OMB. Section B reports on the means by which the public participated in the review process and provided comments. Sections C and D, respectively, report on research efforts that have been conducted as part of this review and the principles that have guided the development of recommendations. Section E outlines the issues that have been under review and reports on decisions reached by MASRC, based on our evaluation of research results and consideration of related public comments. Section F provides a comparison of the current metropolitan area standards with the standards recommended by MASRC. Section G presents the specific standards recommended by MASRC. Finally, Section H provides definitions of key terms used in the report.

We hope that OMB will find this report with its accompanying recommendations informative and helpful in making its decision on what changes, if any, to adopt in the standards for defining geographic areas for collecting, tabulating, and publishing Federal statistics. Attachment

### **Report to the Office of Management and Budget on the Review of the Metropolitan Area Standards and Recommendations for Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century**

#### **A. Formation of the Metropolitan Area Standards Review Committee**

In fall 1998, the Office of Management and Budget (OMB) reconstituted the Federal Executive Committee on Metropolitan Areas as the Metropolitan Area Standards Review Committee (MASRC). Agencies represented on MASRC include the Census Bureau (Chair), Bureau of Economic Analysis, Bureau of Labor Statistics, Bureau of Transportation Statistics, Economic Research Service (Agriculture), National Center for Health Statistics, and *ex officio*, OMB.

OMB charged MASRC with the tasks of examining the current (1990)

metropolitan area (MA) standards and alternative approaches to statistical definitions of metropolitan and nonmetropolitan areas and providing recommendations to OMB for possible changes to the current standards. Completion of this charge required: (1) Identifying current statistical uses of MAs and assessing whether and how those uses might better be met; (2) reviewing the conceptual underpinnings of the current MA standards and their continued usefulness; (3) assessing the extent to which any changes in the standards should reflect changes in computing technology on how MAs are or can be defined and maintained; (4) developing and empirically testing potential changes in the standards; and (5) ensuring ample opportunity for widespread public participation in the review process.

## B. Public Participation and Comments

Public participation and comments, obtained through a variety of formats, have provided important guideposts for the review of the MA standards. Beginning early in the decade, OMB and Census Bureau staff received comments and suggestions from Federal, State, and local officials; representatives of the private sector; researchers; and other data users through meetings, responses to presentations at academic and professional conferences, and at a Congressional hearing held in July 1997.

OMB requested formal public comment on MA concepts and standards through the **Federal Register** Notice "Alternative Approaches to Defining Metropolitan and Nonmetropolitan Areas," that was published on December 21, 1998. During the public comment period for the Notice, a seminar and open forum were held in Alexandria, Virginia, on January 21 and 22, 1999. Comments received in response to the Notice and at the seminar and open forum were considered by MASRC during its development of recommendations.

Between January and August 1999, Census Bureau staff also participated in, and offered presentations at, some 20 meetings and conferences around the country attended by Federal statistical program participants, State and local officials, and experts in academia and private survey and research firms. Many individuals also have contacted OMB and Census Bureau staff to discuss issues pertaining to this review. Although comments received in these ways were not part of the official set of written responses to the December 1998 **Federal Register** Notice, MASRC was apprised of and considered these less formal comments in its deliberations.

## C. Review Process

### 1. Metropolitan Area Standards Review Project

The MA standards are reviewed and, if warranted, revised in the years preceding each decennial census to ensure their continued usefulness and relevance. The current review of the MA standards—the Metropolitan Area Standards Review Project (MASRP)—is the sixth such review. This review has been especially thorough, reflecting as a first priority users' concerns with the conceptual and operational complexity of the standards that have evolved over the decades. Other key concerns of MASRP have been: (1) Whether modifications to the standards over the years have permitted them to stay abreast of changes in population distribution and activity patterns; (2) whether advances in computer applications permit consideration of new approaches to defining areas; and (3) whether there is a practicable way to capture a more complete range of U.S. settlement and activity patterns than the current MA standards capture.

Specific, major issues addressed by MASRP have included:

- Whether the Federal Government should define metropolitan and nonmetropolitan statistical areas;
- The geographic units—"building blocks"—that should be used in defining the statistical areas;
- The criteria that should be used to aggregate the building blocks in defining the statistical areas;
- Whether the statistical areas should account for all territory of the Nation;
- Whether there should be hierarchies or multiple sets of statistical areas in the classification;
- The kinds of areas that should receive official recognition in the classification;
- Whether the classification should reflect statistical rules only or allow a role for local opinion; and
- How frequently statistical areas should be updated.

As in previous decades, the Census Bureau has worked closely with OMB in support of the MA program. In 1990, the Census Bureau commissioned four studies by scholars to sketch out and evaluate alternative approaches to defining metropolitan and nonmetropolitan areas. The reports produced through these studies were published in a Census Bureau working paper, which later served as the focus of discussion at an open conference in November 1995 that was hosted by the Council of Professional Associations on Federal Statistics (COPAFS) and attended by representatives of Federal,

State, and local government agencies; the private sector; universities; and citizens' organizations.

The Census Bureau has conducted research into a variety of issues related to metropolitan and nonmetropolitan area concepts and criteria as part of MASRP. The first phase of this research culminated in publication of the four alternative approaches to defining metropolitan and nonmetropolitan areas presented for public comment in the **Federal Register** Notice of December 21, 1998. The second phase of the research extended the earlier work, but with a particular focus on providing information directly to MASRC and answering specific questions raised during MASRC's review of the standards.

In addition to research conducted or contracted by the Census Bureau, other researchers both inside and outside the Federal Government have investigated alternative methods for defining metropolitan and nonmetropolitan areas during the past decade. Researchers in the Department of Agriculture's Economic Research Service (ERS) investigated the feasibility of using census tracts as building blocks for MAs in conjunction with current (1990) MA standards. Researchers at the University of Washington, in a project jointly funded by the Department of Health and Human Services' Office of Rural Health Policy and ERS, have contributed further to development of an alternative method of defining metropolitan and nonmetropolitan areas using census tracts as building blocks. Researchers at the University of Minnesota continued investigation of the comparative density approach first proposed early in this decade and presented at the 1995 conference.

### 2. 1995 Conference on New Approaches to Defining Metropolitan and Nonmetropolitan Areas

Discussion at the 1995 conference considered widely ranging views, but there was general agreement on the following issues:

- The Federal Government should define standard areas at the metropolitan and nonmetropolitan area level.
- Because of data availability and familiarity, areas should be defined using the county as the fundamental unit. To foster greater precision and to meet special-purpose needs, areas based on sub-county entities also should be defined. There were suggestions that multiple sets of areas using different units should be provided, along with documentation on appropriate uses.

- Statistical areas defined following Census 2000 should cover the entire territory of the country and should better account for the full range of settlement patterns than do the current MAs and their nonmetropolitan "residual."

- Areas should be defined using a consistent set of rules for the entire country.

- Familiar components of settlement, such as major population and employment centers as represented by current MA definitions, should be in evidence in the new system.

- Commuting (journey-to-work) data from the Census Bureau should continue as the principal measure for determining the extent of areas. Other data—including electronic media and newspaper market penetration data, local traffic study data, and wholesale distribution data—are available and usable for specific purposes. Population and housing unit density also were viewed as potential measures for some purposes, and employment density received mention.

A detailed summary of the conference appears as Appendix C in the December 21, 1998 **Federal Register** Notice; the summary also is available from the Census Bureau at (301) 457-2419.

### 3. January 1999 Seminar and Open Forum: Metropolitan and Nonmetropolitan Areas for a New Decade

During the comment period following publication of the December 1998 **Federal Register** Notice, COPAFS hosted a seminar and open forum focusing on the four alternative approaches to defining metropolitan and nonmetropolitan areas presented in that Notice. The two-day seminar/open forum provided a venue for disseminating information and receiving comments related to the review of the standards.

On the first day, one session was devoted to each of the four approaches. Census Bureau staff presented an overview of the approach; outside experts then described benefits and potential problems. Discussion periods provided opportunities for all attendees to offer comments and raise questions. On the second day, prepared statements were provided by several individuals, and participants engaged in a general discussion of the standards review.

There was agreement at the seminar/open forum that MAs are widely recognized and used (although the specifics of MA standards are less clear to many individuals), and that OMB should continue to define MAs. Some participants expressed a preference for a

single classification system (as opposed to multiple systems, as suggested at the 1995 conference) to avoid confusion among users and to ensure that the classification is useful to as many data users as possible.

The relative merits of using counties versus census tracts as the building blocks for statistical areas were key to the discussion. Some Federal agencies, researchers, and others noted growing interest in identifying metropolitan and nonmetropolitan territory and population with greater geographic resolution than can be achieved with the current, largely county-based MAs. Many commenters supported the continued use of counties when defining metropolitan and nonmetropolitan areas because of the range and quality of data available for counties and the relative ease in comparing county-level data over time.

In addition, many participants agreed that commuting, despite its inability to account for all patterns of activity, remains the preferred means of measuring integration of areas and should continue to be the measure used to determine the geographic extent of entities. Although other measures have been used in the past or considered in MASRP, most seminar/open forum participants agreed that Census Bureau commuting information currently provides the most reliable and exhaustive source of data for this purpose. Interest was expressed in the use of directional commuting as a means of measuring the integration of entities, but some participants suggested that it was too complicated for use in defining metropolitan and nonmetropolitan areas.

A complete summary of the seminar/open forum is available from the Census Bureau at (301) 457-2419.

### D. Principles Guiding the Review and Development of Recommendations

Several guiding principles framed discussion of the issues under review and formulation of specific recommendations. MASRC sought to develop a classification that would capture and portray effectively the distribution of population and economic activity across the United States and Puerto Rico. This classification must meet the needs of both producers and users of data. Also, the criteria used to define the areas must be applicable nationwide using publicly available data. Finally, MASRC sought to prepare criteria that were simpler than those in the current MA standards.

### E. Issues Under Review

MASRC's review and its recommendations to OMB have drawn upon previous research conducted by the Census Bureau, other agencies, and individuals. The review also has benefited from discussions at the November 1995 conference and the January 1999 seminar/open forum, and from comments received in response to OMB's December 21, 1998 **Federal Register** Notice. This section presents MASRC's recommendations to OMB for changing the MA standards. It also presents a discussion of the major issues considered during the review.

#### Summary of Recommendations

MASRC recommends adoption of a *Core-Based Statistical Area (CBSA) Classification* that includes Megapolitan, Macropolitan, and Micropolitan Areas, with each area containing one or more population cores of at least 10,000 persons (see Section E.1). Census Bureau-defined urbanized areas (UAs) and a proposed new geographic entity for Census 2000—Census Bureau-defined settlement clusters (SCs)—are these cores. UAs are continuously built-up areas comprising a central place (or places) and the densely settled surrounding territory that together have a population of at least 50,000 and, generally, an overall population density of at least 1,000 persons per square mile. SCs will extend the UA concept to smaller concentrations of at least 10,000 population. Territory outside of Megapolitan, Macropolitan, and Micropolitan Areas should be termed "Outside CBSAs."

MASRC recommends using counties and equivalent entities as building blocks of CBSAs throughout the United States and Puerto Rico (Section E.2). Minor civil divisions (MCDs) should be used as building blocks for an alternative set of areas in New England only.

Those counties containing the cores, MASRC recommends, should become the *central counties* of CBSAs (Section E.3). MASRC also recommends that only commuting data should be used to aggregate counties beyond central counties—the *outlying counties*—to form CBSAs. A single minimum commuting threshold of 25 percent should be used to qualify a county for inclusion as outlying in a particular CBSA (Section E.4).

*Mergers* of adjacent CBSAs to form a single CBSA should take place when commuting data indicate that strong ties exist between the two areas' central counties (Section E.6). *Combinations* of

adjacent CBSAs should take place when there are weaker but still important commuting ties between entire CBSAs. The CBSAs that are combined should retain separate identities in addition to being recognized as parts of *Combined Areas* (Section E.7).

MASRC recommends identifying the city with the largest population in each CBSA, as well as any additional cities with large population or employment totals, as *principal cities* (Section E.8). The title of each CBSA should include the name of the largest principal city. If there are multiple principal cities in a CBSA, the names of the second largest and third largest principal cities should be included in the title, in order of descending population size (Section E.9).

These recommendations and others are described in greater detail below.

### Notes on Data and Maps

In carrying out its work, MASRC used 1990 census data to model the possible outcomes of its recommendations for geographic area definitions. The four maps accompanying this section were developed using 1990 census data and the recommended standards. Because SCs are proposed new geographic areas for presentation of Census 2000 data, incorporated places and census designated places (CDPs) of 10,000 to 49,999 population were used for research purposes. The maps are for illustrative purposes only and are not intended to portray the extent of areas that would be defined using Census 2000 data and the recommended standards.

### Detailed Recommendations

#### 1. Recommendations Concerning Levels of Statistical Areas Recognized Within the Core-Based Statistical Area Classification

MASRC recommends a *Core-Based Statistical Area (CBSA) Classification* to replace the current MA classification. MASRC recommends the following terms and levels, based on the total population in the cores of CBSAs (and not based on the total population of a CBSA):

Core-Based Statistical Areas	Population in Cores
Megapolitan Areas ....	1,000,000 and above
Macropolitan Areas ...	50,000 to 999,999
Micropolitan Areas ....	10,000 to 49,999

*Territory not included in CBSAs should be designated as Outside Core-Based Statistical Areas.*

MASRC addressed several, sometimes incompatible, concerns as it developed terminology and size levels:

(1) Eliminating the current metropolitan/nonmetropolitan dichotomy and replacing it with a range of categories that more meaningfully represent the settlement and activity patterns of the Nation;

(2) Introducing specific terms for areas containing cores of 1,000,000 or more persons and cores of 250,000 to 999,999 persons, respectively;

(3) Evaluating advantages and disadvantages of retaining the current MA standards' core population threshold of 50,000;

(4) Assessing advantages and disadvantages of retaining the current MA standards' metropolitan/nonmetropolitan terminology; and

(5) Maintaining simplicity.

With regard to the first two considerations, there was broad agreement within MASRC that the 1,000,000-person threshold was a significant delimiter between large urban areas and other areas. Under the proposed standards, 35 areas, each containing one or more cores that together have 1990 decennial census populations of 1,000,000 or more, would account for about 45 percent of the 1990 U.S. population.

Broad agreement also existed in favor of establishing a micropolitan category as a means of distinguishing between (1) areas integrated with smaller population centers and (2) territory not integrated with any particular population center. Defining Micropolitan Areas represents a response to comments that a new classification should cover a broader range of population and economic activity patterns than the current MA standards do. MASRC also considered various combinations of population distribution and economic activity pattern measures to classify counties not included in a CBSA, but none offered a satisfactory method of meaningfully accounting for these counties in the new classification.

The large core population range (50,000 to 999,999) of the macropolitan level could limit its utility for analytical and statistical purposes. An option would be to split this level into two categories, one identifying areas with cores that together have populations of 50,000 to 249,999 ("mesopolitan areas") and the other identifying areas with cores that together have populations of 250,000 to 999,999 ("macropolitan areas"). Although there was support for this option, there also was concern that the use of five levels (including "Outside CBSAs") might make the system too complex.

Some members of MASRC expressed the view that the 50,000-person threshold used in the current MA standards held greater significance when first adopted by the Census Bureau for defining "metropolitan districts" in 1930 than it does now. The national population has more than doubled since 1930, and these members reasoned that the resulting increase in the number of places of 50,000 population or more has reduced the meaning of this threshold in identifying areas of metropolitan character. Changes in economic structure also have made places of this size less self-reliant than they were in the past. On the other hand, MASRC members observed that retaining the 50,000 person threshold would offer maximum continuity with current and previous definitions of MAs.

Some MASRC members favored retaining metropolitan/nonmetropolitan terminology for use with CBSAs, identifying Megapolitan and Macropolitan Areas as metropolitan and identifying Micropolitan Areas and counties Outside CBSAs as nonmetropolitan. The reasoning behind this position was that identification of metropolitan and nonmetropolitan areas within the CBSA Classification would provide continuity with areas defined under the current standards and might be of benefit to some producers and users of data. Members favoring this position noted that the top two levels, when combined, approximate the MAs defined under the current standards and that the lower two levels, when combined, approximate areas currently referred to as nonmetropolitan. Others argued that continued identification of areas as metropolitan and nonmetropolitan might reduce the value of the levels provided by the CBSA classification, in elaborating on the current metropolitan/nonmetropolitan dichotomy. Members also suggested that some data users might find value in analyzing the distribution of population and economic activities across Megapolitan, Macropolitan, and Micropolitan Areas as a group and that separation of these levels by a metropolitan/nonmetropolitan dichotomy would discourage such uses.

#### 2. Recommendations Concerning the Geographic Unit To Be Used as the Building Block for Defining CBSAs

MASRC recommends using counties and equivalent entities as building blocks for CBSAs throughout the United States and Puerto Rico.

Using counties and equivalent entities throughout the United States and Puerto Rico continues current practice, except

in New England, where MCD-based areas currently constitute the official MAs.

The choice of a geographic unit to serve as the building block can affect the geographic extent of a statistical area and its relevance or usefulness in describing economic and demographic patterns. The choice also has implications for the ability of Federal agencies to provide data for statistical areas and their components. The December 1998 **Federal Register** Notice presented advantages and disadvantages of five potential building blocks. Each of these units was evaluated in terms of its consistency in delineation across the Nation, data availability, boundary stability, and familiarity.

Counties and their equivalents are major and familiar geographic units of government, performing a wide range of functions, and a wide range of statistically reliable data is available for them. Far more Federal statistical programs produce data at the county level than at any sub-county level. In addition, the use of counties eases comparison with current and past MA definitions. MASRC decided that the well-known disadvantages of counties as building blocks for statistical areas—the large geographic size of some counties and the lack of geographic precision that follows from their use—were outweighed by the advantages offered by counties.

*MASRC recommends using MCDs as building blocks for an alternative set of areas identified in New England only.*

At a time when development and maintenance of nationwide data bases have long since become routine, use of consistent geographic building blocks in all parts of the country offers improved usability to producers and users of data. Some statistical programs regard the current MA program's use of MCDs—cities and towns—in New England as a hindrance; others avoid difficulties posed by the MCD-based areas by using the current alternative county-based areas for New England, known as the New England County Metropolitan Areas. Demographic and economic data for MCDs in New England, however, are more plentiful than for sub-county entities in the rest of the Nation. Cities and towns are the primary units of local government in New England (counties in Connecticut and Rhode Island, and some counties in Massachusetts, no longer possess legal or functional status). In reaching its recommendation to extend the use of counties as building blocks for the primary set of statistical areas in New England, MASRC attached priority to the desire for use of a single, consistent geographic unit nationwide.

In recognition of the importance of MCDs in New England, the wide availability of data for them, and their long-term use in the MA program, MASRC recommends using MCDs as building blocks for an alternative set of areas for the six New England states.

### *3. Recommendations Concerning Cores of CBSAs and Central Counties*

*MASRC recommends using Census Bureau-defined UAs of 50,000 or more population and Census Bureau-defined SCs of at least 10,000 population as cores of CBSAs. MASRC also recommends identifying "central counties" based on the locations of the cores.*

The recommended use of UAs as cores is consistent with current practice. The use of SCs proposed for Census 2000 reflects MASRC's recommendation to extend the classification to areas based on cores of 10,000 to 49,999 population. This change would permit a fuller accounting for the distribution of population and economic activity across the territory of the Nation than is provided by the current MA standards. Following from this recommendation, the presence of a core (UA or SC) of at least 10,000 population should be required for defining a CBSA.

The locations of UAs and SCs should provide the basis for identifying *central counties* of CBSAs—the counties to and from which ties are measured in determining the extent of areas. MASRC recommends identifying central counties as those counties:

- (a) That have at least 50 percent of their population in UAs or SCs or both; or
- (b) That have within their boundaries at least 50 percent of the population of a UA or SC that crosses county boundaries.

### *4. Recommendations Concerning Criteria for Inclusion of Outlying Counties*

*MASRC recommends using commuting data as the basis for aggregating counties to form CBSAs (i.e., to qualify "outlying counties"). MASRC recommends not using measures of settlement structure, such as population density, to qualify outlying counties for inclusion in CBSAs.*

Three priorities guided the committee in reaching these recommendations. First, the data used to measure connections among counties should describe those connections in a straightforward and intuitive manner. Second, data for the measure should be collected using consistent procedures nationwide. Third, the data should be readily available to the public. These

priorities pointed to the use of data gathered by Federal agencies and more particularly to commuting data from the Census Bureau. Commuting to work is an easily understood measure that reflects the social and economic integration between geographic areas.

The recommendation not to use measures of settlement structure represents a change from the current MA standards. In those standards, varying levels of population density, percentage of total population that is urban, presence of UA population, and population growth rate are used in combination with varying levels of commuting to determine qualification of outlying counties for inclusion in an MA. MASRC concluded that as changes in settlement and commuting patterns as well as changes in communications technologies have occurred, settlement structure no longer is as reliable an indicator of metropolitan character as was previously the case.

*MASRC recommends qualifying an outlying county on the basis of the percentage of employed residents of the county who work in the CBSA's central county or counties, or on the basis of the percentage of employment in the potential outlying county accounted for by workers who reside in the CBSA's central county or counties. MASRC recommends using a 25 percent minimum threshold for both measures.*

MASRC observed that the percentage of a county's employed residents who commute to the central county or counties is an unambiguous, clear measure of whether a potential *outlying county* should qualify for inclusion. The percentage of employment in the potential outlying county accounted for by workers who reside in the central county or counties is a similarly straightforward measure of ties. Including both criteria addresses both the conventional and the less common reverse commuting flows.

The percentage of workers in the United States who commute to places of work outside their counties of residence has increased from approximately 15 percent in 1960 (when nationwide commuting data first became available from the decennial census) to nearly 25 percent in 1990. In addition, the 25 percent threshold stood out as a noticeable divide when reviewing 1990 census data concerning the percentage of workers who commute outside their counties of residence. MASRC concluded that the pattern in commuting rates and increases in intercounty commuting over the past 40 years warranted a comparable increase from the 15 percent minimum commuting threshold currently used to



qualify counties—under specified circumstances—for inclusion in MAs.

*MASRC recommends that counties qualify for inclusion in a CBSA as outlying counties on the basis of commuting ties with the central county (or counties) of that one area only.*

MASRC concluded that outlying counties should not qualify based on total commuting to central counties of multiple CBSAs because that would result in inconsistent grounds for qualification in an individual area. Throughout its history, the purpose of the MA program has been to identify individual statistical areas, each containing a core plus any surrounding territory integrated with that core as measured by commuting ties. MASRC saw no reason to depart from that approach in defining CBSAs.

#### *5. Recommendation Concerning Use of Statistical Rules and the Role of Local Opinion*

*MASRC recommends limited use of local opinion in the definition process.*

Applying only statistical rules when defining areas minimizes ambiguity and maximizes the replicability and integrity of the process. MASRC recommends consideration of local opinion only in cases of CBSA combinations where adjacent CBSAs meet specified requirements (see E.7 below).

Local opinion should be obtained through the appropriate congressional delegation. Members of the congressional delegation should be urged to contact a wide range of groups in their communities, including business or other leaders, chambers of commerce, planning commissions, and local officials, to solicit comments on the specific combination at issue. MASRC also recommends that OMB use the Internet to make available information pertaining to the potential combination on which local opinion is sought. After a decision has been made, OMB should not request local opinion again on the same issue until the next redefinition of CBSAs.

#### *6. Recommendation Concerning Merging Adjacent CBSAs*

*MASRC recommends “merging” adjacent CBSAs to form a single CBSA when the central county or counties of one area qualify as outlying to the central county or counties of another.*

MASRC determined that when the central county or counties (as a group) of one CBSA qualify as outlying to the central county or counties (as a group) of another area, the two CBSAs should be merged. Given the strong ties demonstrated in a merger, the

individual areas should not retain separate identities within the merged entity; rather, the merged entity should be recognized as a single CBSA.

Because a merger recognizes ties similar to the ties between an outlying county and the central counties of a CBSA, MASRC recommends that the minimum commuting threshold similarly be set at 25 percent, measured with respect to all central counties of one CBSA relative to all central counties of the other.

#### *7. Recommendation Concerning Combining Adjacent CBSAs*

*MASRC recommends “combining” CBSAs when entire adjacent areas are linked through commuting ties.*

MASRC recommends that ties between adjacent CBSAs that are less intense than those captured by mergers (see Section E.6), but still significant, be recognized by combining those CBSAs. Because a combination thus defined represents a relationship of moderate strength between two CBSAs, the areas that combine should retain separate identities within the larger combined area. Potential combinations should be evaluated by measuring commuting between entire adjacent CBSAs—commuting of all counties, as a group, within one CBSA relative to all counties, as a group, in the adjacent area.

MASRC recommends basing combinations on the *employment interchange rate* between two CBSAs, defined as the sum of the percentage of commuting from the smaller area to the larger area and the percentage of employment in the smaller area accounted for by workers residing in the larger area. MASRC recommends a minimum threshold of 15 for the employment interchange rate, but recognizes that this threshold may result in combinations where the measured ties are perceived as minimal by residents of the two areas. Therefore, MASRC recommends combinations of CBSAs, based on an employment interchange rate of at least 15 but less than 25, only if local opinion in both areas favors the combination. If the employment interchange rate equals or exceeds 25, combinations should occur automatically.

#### *8. Recommendation Concerning Identification of Principal Cities Within the Core-Based Statistical Area Classification*

*MASRC recommends identifying principal cities in CBSAs.*

Because the procedures recommended by MASRC identify UAs and SCs as the organizing entities for CBSAs, the

identification of central cities—required by the current MA standards for defining areas—is no longer necessary. Also, while still important, central cities have become less dominant in the local context over time. Nevertheless, MASRC recognizes that specific cities within individual CBSAs are important for analytical purposes as centers of employment, trade, entertainment, and other social and economic activities. MASRC, therefore, includes in the recommended standards criteria for identifying principal cities and using the principal cities for titling areas.

MASRC recommends that the principal city (or cities) of a CBSA should include: (1) the largest incorporated place or census designated place (CDP) in the CBSA; (2) any additional incorporated place or CDP with a population of at least 250,000 or in which 100,000 or more persons work; and (3) any additional incorporated place or CDP with a population that is at least 10,000 and one-third the size of the largest place, and in which employment meets or exceeds the number of employed residents.

MASRC recommends using the term “principal city” rather than “central city.” The term “central city” has come to connote “inner city” and thus sometimes causes confusion.

#### *9. Recommendations Concerning Titles of Core-Based Statistical Areas and Combined Areas*

*MASRC recommends titling each CBSA using the name of the principal city with the largest population, as well as the names of the second- and third-largest principal cities, if multiple principal cities are present. MASRC also recommends titling each Combined Area using the name of the largest principal city in each of up to three CBSAs that combine, in descending order of CBSA population size.*

Titles provide a means of uniquely identifying individual CBSAs and Combined Areas so that each is recognizable to a variety of data users. As such, the title of a CBSA or Combined Area should contain the name or names of geographic entities located within the area that are prominent and provide data users with a means of easily identifying the general location of the CBSA. Use of the names of principal cities also provides a link to the (named) UAs and SCs that form the cores of CBSAs. Finally, the State(s) in which the CBSA or Combined Area is located also should be included in the title.

*10. Recommendation Concerning Categories Describing Settlement Structure Within the Core-Based Statistical Area Classification*

*MASRC recommends not defining urban, suburban, rural, exurban, and so forth, within the CBSA Classification.*

MASRC recognizes that formal definitions of categories such as inner city, inner suburb, outer suburb, exurban, and rural would be of use to the Federal statistical system as well as to researchers, analysts, and other users of Federal data. Such categories, however, are not necessary for the delineation of statistical areas that describe the functional ties between geographic entities. These additional categories would more appropriately be included in a separate classification that focuses exclusively on describing settlement patterns and land uses.

MASRC recommends continuing research by the Census Bureau and other interested Federal agencies on sub-county settlement patterns to describe further the distribution of population and economic activity throughout the Nation.

*11. Recommendations Concerning "Grandfathering" of Current Metropolitan Areas*

*MASRC recommends that the definitions of current MAs not be automatically retained ("grandfathered") in the CBSA Classification. MASRC also recommends that the current status of individual counties as metropolitan or*

*nonmetropolitan not be considered when re-examining all counties using the recommended standards.*

In this context, "grandfathering" refers to the continued designation of an area even though it does not meet the standards currently in effect. The current (1990) MA standards permit changes in the definitions, or extent, of individual MAs through the addition or deletion of counties on the basis of each decennial census, but the standards do not permit the disqualification of MAs that previously qualified on the basis of a Census Bureau population count. To maintain the integrity of the classification, MASRC favors the objective application of the recommended standards rather than continuing to recognize areas that do not meet the standards that currently are in effect. MASRC recommends that the current status of a county as either metropolitan or nonmetropolitan play no role in the application of the recommended standards.

*12. Recommendations Concerning Intercensal Update Schedule*

*MASRC recommends designating new CBSAs intercensally on the basis of Census Bureau population estimates or special censuses for places. MASRC also recommends updating the extent of CBSAs on the basis of commuting data from the Census Bureau's American Community Survey, available for all counties beginning in 2008.*

The frequency with which new statistical areas are designated and existing areas updated has been of

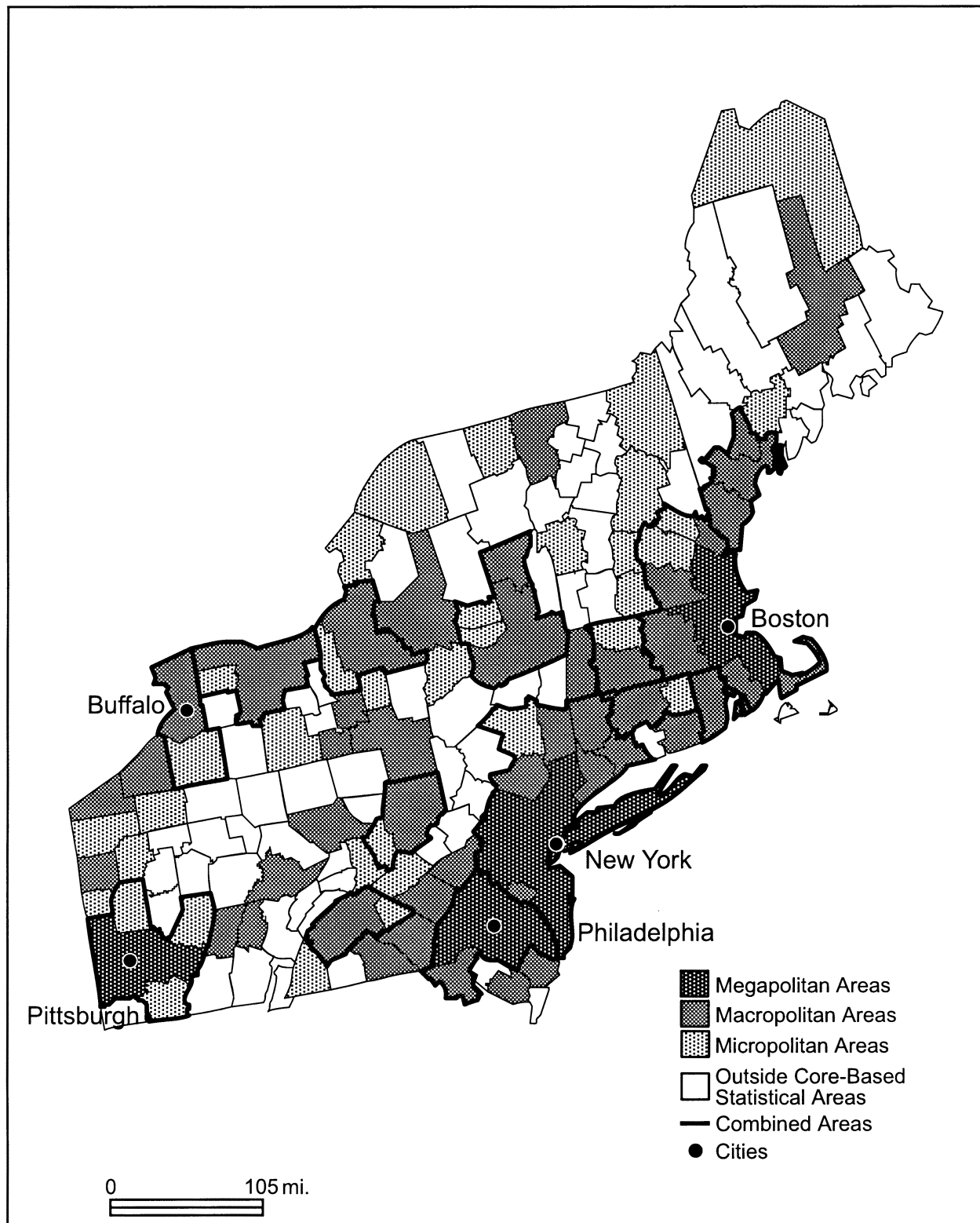
considerable interest among producers and users of data for MAs. The sources and future availability of data for updating areas figured prominently in MASRC's discussions. The availability of population totals and commuting data affects the ability to identify new statistical areas, move existing areas between categories, and update the extent of existing areas.

The current standards provide for the designation of a new MA on the basis of a population estimate or a special census count for a city. This approach for designating new areas intercensally would continue to provide the most consistent and equitable means of qualifying new CBSAs in the future. A new CBSA should be designated if a city that is outside any existing CBSA has a Census Bureau population estimate of 10,000 or more for two consecutive years, or a Census Bureau special census count of 10,000 or more population. (Currently, population estimates for existing and potential UAs and SCs are not produced.) A new CBSA also should be designated if a special census results in delineation of an intercensal UA or SC of 10,000 or more population.

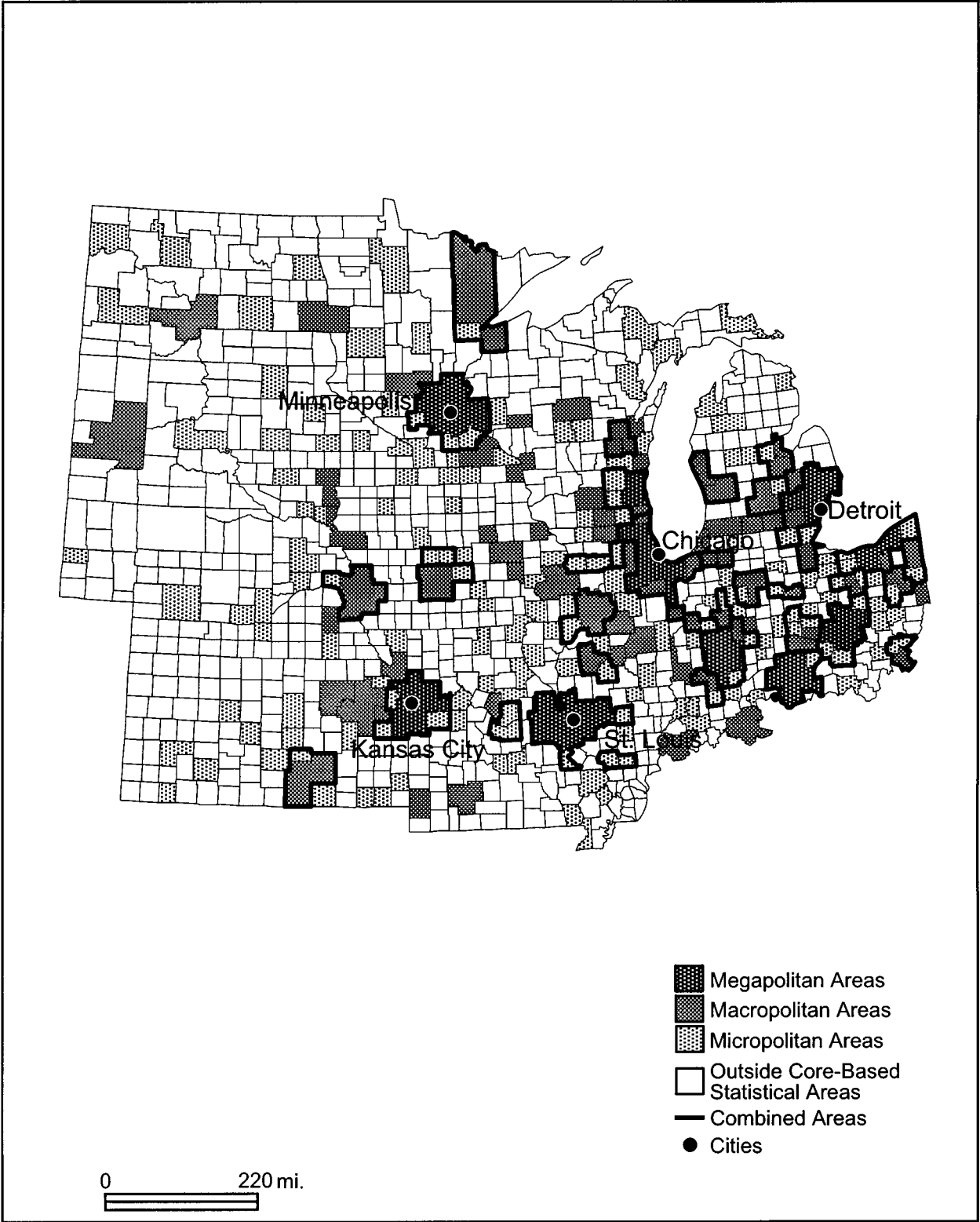
The composition of all existing CBSAs should be updated in 2008 using commuting data for each county from the Census Bureau's American Community Survey, averaged over five years and centered on 2005. This update would affect only counties identified as outlying.

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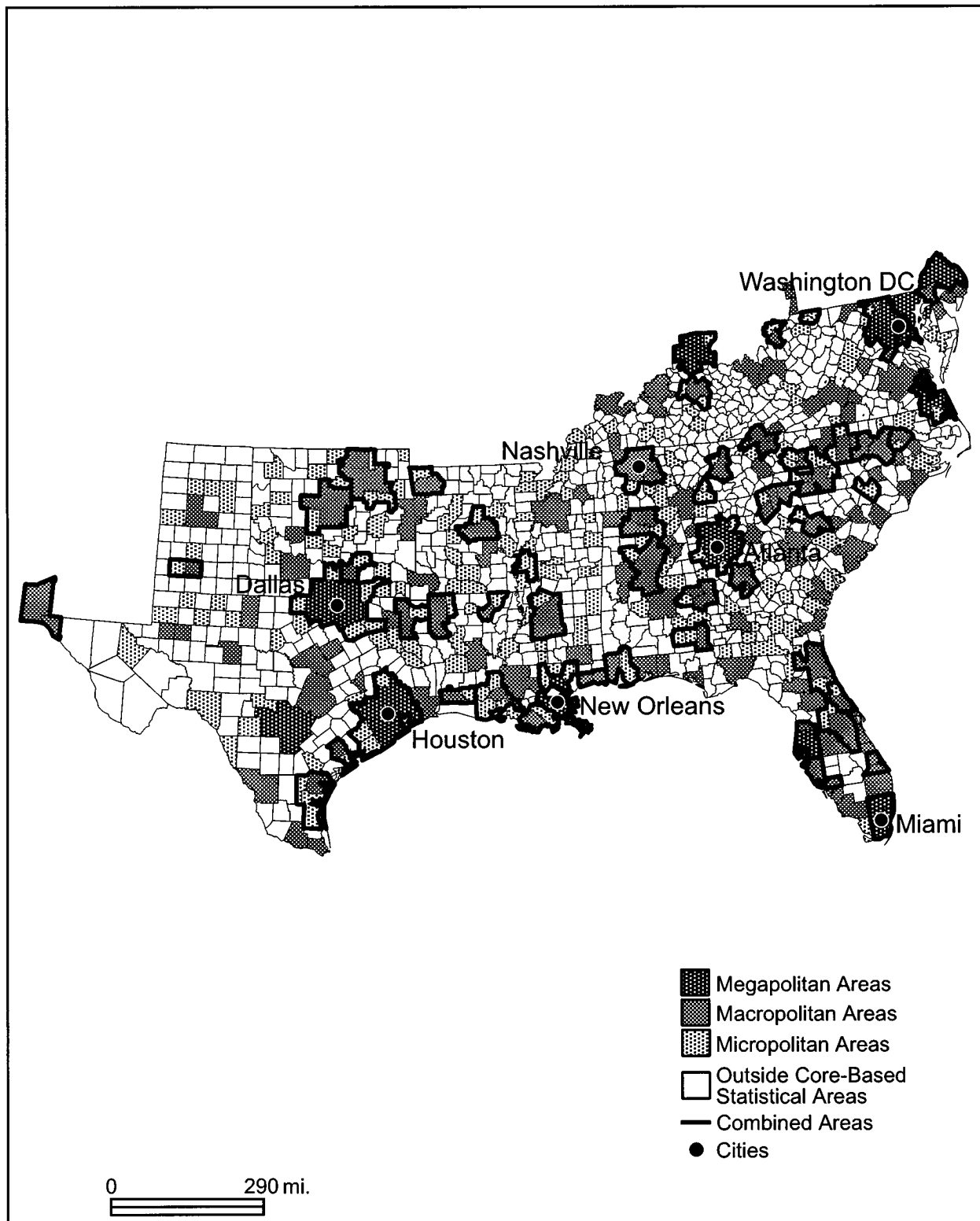
Core-Based Statistical Area Classification  
Northeast Region



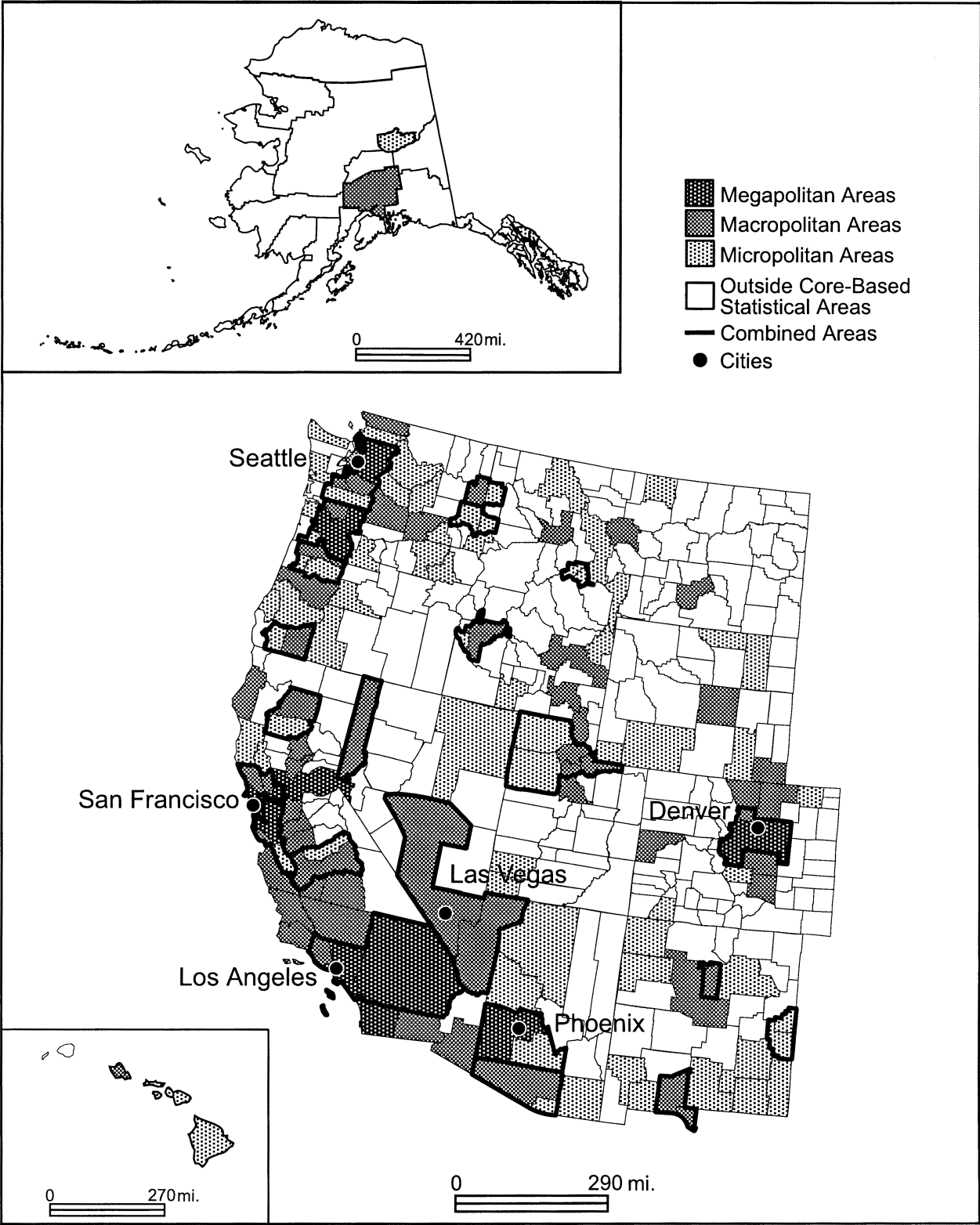
Core-Based Statistical Area Classification  
Midwest Region



Core-Based Statistical Area Classification  
South Region



Core-Based Statistical Area Classification  
West Region



**F. Comparison of Current Metropolitan Area Standards with the Recommended Core-Based Statistical Area Standards**

	Current standards	Recommended standards
Terms and Levels .....	Identification of Metropolitan Areas (MAs) comprising Metropolitan Statistical Areas (MSAs), Consolidated Metropolitan Statistical Areas (CMSAs), and Primary Metropolitan Statistical Areas (PMSAs). MSAs and PMSAs are identified as level A, B, C, or D areas. MSAs of 1,000,000 or more population can be designated as CMSAs if local opinion is in favor and component PMSAs can be identified.	Identification of Core-Based Statistical Areas (CBSAs) comprising Megapolitan Areas, Macropolitan Areas, and Micropolitan Areas. Counties that are not included in a Megapolitan, Macropolitan, or Micropolitan Area are classified as Outside CBSAs. CBSAs are not subdivided into component parts.
Building Blocks .....	Counties and equivalent entities throughout U.S. and Puerto Rico, except in New England where cities and towns are used to define MAs. County-based alternative provided for New England States.	Counties and equivalent entities throughout U.S. and Puerto Rico. City-and-town-based alternative provided for New England States.
Qualification of Areas .....	City of at least 50,000 population, or Census Bureau-defined urbanized area (UA) of at least 50,000 population in an MA of at least 100,000 population.	Census Bureau-defined settlement cluster (SC) of at least 10,000 population or UA of at least 50,000 population.
Qualification of Central Counties.	Any county that includes a central city or at least 50% of the population of a central city that is located in a qualifier UA. Also any county in which at least 50% of the population is located in a qualifier UA.	Any county in which at least 50% of the population is located in UAs and SCs, or that has within its boundaries at least 50% of the population of a UA or SC that crosses county boundaries.
Qualification of Outlying Counties.	Combination of commuting and measures of settlement structure <ul style="list-style-type: none"> <li>• 50% or more of employed workers commute to the central county/counties of an MSA and: 25 or more persons per square mile (ppsm), or at least 10% or 5,000 of the population lives in a qualifier UA; OR</li> <li>• 40% to 50% of employed workers commute to the central county/counties of an MSA and: 35 or more ppsm, or at least 10% or 5,000 of the population lives in qualifier UA; OR</li> <li>• 25% to 40% of employed workers commute to the central county/counties of an MSA and: 35 ppsm and one of the following: (1) 50 or more ppsm, (2) at least 35% urban population, (3) at least 10% or 5,000 of population lives in qualifier UA; OR</li> <li>• 15% to 25% of employed workers commute to the central county/counties of an MSA and: 50 or more ppsm and two of the following: (1) 60 or more ppsm, (2) at least 35% urban population, (3) population growth rate of at least 20%, (4) at least 10% or 5,000 of population lives in qualifier UA; OR</li> <li>• 15% to 25% of employed workers commute to the central county/counties of an MSA and less than 50 ppsm and two of the following: (1) at least 35% urban population, (2) population growth rate of at least 20%, (3) at least 10% or 5,000 of population lives in qualifier UA.</li> </ul> <p>If a county qualifies as outlying to two or more MAs, it is assigned to the area to which commuting is greatest; if the relevant commuting percentages are within 5 points of each other, local opinion is considered.</p>	At least 25% of the employed residents of the county work in the central county/counties of a CBSA; or at least 25% of the employment in the county is accounted for by workers residing in the central county/counties of the CBSA. A county that qualifies as outlying to two or more CBSAs will be included in the area with which it has the strongest commuting tie.
Local Opinion .....	Consulted when: <ul style="list-style-type: none"> <li>• a county qualifies as outlying to two different MSAs and the relevant commuting percentages within 5 points of each other;</li> <li>• a city or town in New England qualifies as outlying to two different MSAs and has relevant commuting percentages within 5 points of each other;</li> <li>• a city or town in New England qualifies as outlying to an MSA but has greater commuting to a nonmetropolitan city or town and the relevant commuting percentages are within 5 points of each other;</li> <li>• combining MSAs whose total population is less than 1,000,000;</li> <li>• assigning titles of MSAs, CMSAs, and PMSAs;</li> <li>• designating PMSAs.</li> </ul>	Consulted only when two CBSAs qualify for combination with an employment interchange rate of at least 15 and less than 25.
Merging Statistical Areas .....	If a county qualifies as a central county of one MSA and as an outlying county on the basis of commuting to a central county of another MSA, both counties become central counties of a single MSA.	Two adjacent CBSAs will be merged to form one CBSA if the central county/counties (as a group) qualify as outlying to the central county/counties (as a group) of the other CBSA.



	Current standards	Recommended standards
Combining Statistical Areas	Two adjacent MSAs are combined as a single MSA if: (A) the total population of the combination is at least one million and (1) the commuting interchange between the two MSAs is equal to at least 15% of the employed workers residing in the smaller MSA, or at least 10% of the employed workers residing in the smaller MSA and the UA of a central city of one MSA is contiguous with the UA of a central city of the other MSA, or a central city in one MSA is included in the same UA as a central city in the other MSA; AND (2) at least 60% of the population of each MSA is urban. (B) the total population of the combination is less than one million and (1) their largest central cities are within 25 miles of one another, or the UAs are contiguous; AND (2) there is definite evidence that the two areas are closely integrated economically and socially; AND (3) local opinion in both areas supports combination.	Two adjacent CBSAs will be combined if the employment interchange rate between the two areas is at least 25. The employment interchange rate is the sum of the percentage of employed residents of the CBSA with the smaller total population who work in the CBSA with the larger population and the percentage of employment in the CBSA with the smaller total population that is accounted for by workers residing in the CBSA with the larger total population. Adjacent CBSAs that have an employment interchange rate of at least 15 and less than 25 may combine if local opinion in both areas favors combination.
Central Cities .....	Central cities include the largest city in an MSA/CMSA AND each city of at least 250,000 population or at least 100,000 workers AND each city of at least 25,000 population and at least 75 jobs per 100 workers and less than 60% out commuting AND each city of at least 15,000 population that is at least 1/3 the size of largest central city and meets employment ratio and commuting percentage above AND largest city of 15,000 population or more that meets employment ratio and commuting percentage above and is in a secondary noncontiguous UA AND each city in a secondary noncontiguous UA that is at least 1/3 the size of largest central city in that UA and has at least 15,000 population and meets employment ratio and commuting percentage above.	Principal cities include the largest incorporated place or census designated place in a CBSA AND each place of at least 250,000 population or in which at least 100,000 persons work AND each place with a population that is at least 10,000 and 1/3 the size of the largest place, and in which employment meets or exceeds the number of employed residents.
Titles .....	Names of up to three central cities in descending order of population size. Local opinion considered under specified conditions.	Names of up to three principal cities in descending order of population size.
Grandfathering .....	An MSA designated on the basis of census data according to standards in effect at the time of designation will not be disqualified on the basis of lacking a city of at least 50,000 population or a UA of at least 50,000 or a total population of at least 100,000.	Areas that do not meet the minimum standards for designation do not qualify.
Intercensal Updating .....	A new MA can be designated intercensally if a city has a Census Bureau population estimate or special census count of at least 50,000 or if a county containing a UA has a Census Bureau population estimate or special census count of at least 100,000. Outlying counties are added to existing MSAs intercensally only when (1) a central city located in a qualifier UA extends into a county not included in the MSA and the population of that portion of the city in the county is at least 2,500 according to a Census Bureau population count or (2) an intercensally designated MSA qualifies to combine with an existing MSA. New central cities can be designated intercensally on the basis of a special census count.	A new CBSA can be designated if a city has a Census Bureau population estimate of 10,000 or more for two consecutive years, or a Census Bureau special census count of 10,000 or more. The geographic extent of each CBSA will be re-examined in 2008 using commuting data from the Census Bureau's American Community Survey.

### G. Recommended Standards for Defining Core-Based Statistical Areas for the First Decade of the 21st Century

A Core-Based Statistical Area (CBSA) is a geographic entity consisting of the county or counties containing one or more cores of at least 10,000 population each, plus adjacent counties having a high degree of social and economic integration with the core(s) as measured by commuting ties.

#### 1. Requirements for Qualification of Core-Based Statistical Areas

Each CBSA must include a Census Bureau-defined urbanized area (UA) of at least 50,000 population or a Census Bureau-defined settlement cluster (SC) of at least 10,000 population.

#### 2. Central Counties

The central county or counties of a CBSA are those counties:

- (a) That have at least 50 percent of their population in UAs or SCs or both, or

- (b) That have within their boundaries at least 50 percent of the population of a UA or SC that crosses county boundaries.

A central county of one CBSA may not be the central county of any other CBSA, but a CBSA may have multiple central counties.

#### 3. Outlying Counties

A county is an outlying county of a CBSA if:

- (a) At least 25 percent of the employed residents of the county work

in the central county or counties of the CBSA; or

(b) At least 25 percent of the employment in the county is accounted for by workers who reside in the central county or counties of the CBSA.

A county may not be included in more than one CBSA. If a county qualifies as a central county in one CBSA and as outlying in another, it will be included in the CBSA in which it is a central county. A county that qualifies as outlying to multiple CBSAs will be included in the CBSA with which it has the strongest commuting tie, as measured by either (a) or (b) above. The counties included in a CBSA must be contiguous; if a county is not contiguous to other counties in the CBSA, it will not be included in the CBSA.

#### 4. Merging of Adjacent Core-Based Statistical Areas

Two adjacent CBSAs will be merged to form one CBSA if the central county or counties (as a group) of one CBSA qualify as outlying to the central county or counties (as a group) of the other CBSA using the measures and thresholds stated in Section 3 above.

#### 5. Terminology and Levels

A CBSA will be assigned a level based on the total population of all the UAs and SCs within the CBSA (not on the total CBSA population). Levels of CBSAs are:

Core-Based Statistical Areas	Total Population in All Cores
Megapolitan Areas ....	1,000,000 and above.
Macropolitan Areas ...	50,000 to 999,999.
Micropolitan Areas ....	10,000 to 49,999.

Counties that are not included in CBSAs will be designated as Outside Core-Based Statistical Areas.

#### 6. Identification of Principal Cities

The principal city (or cities) of a CBSA will include:

(a) The largest incorporated place or census designated place in the CBSA;

(b) Any additional incorporated place or census designated place with a population of at least 250,000 or in which 100,000 or more persons work; and

(c) Any additional incorporated place or census designated place with a population that is at least 10,000 and one-third the size of the largest place, and in which employment meets or exceeds the number of employed residents.

#### 7. Titles of Core-Based Statistical Areas

The title of a CBSA will include the name of the principal city with the

largest Census 2000 population. If there are multiple principal cities, the names of the second-largest and third-largest principal cities will be included in the title in descending order of population.

The title also will include the name of the State in which the CBSA is located. If the CBSA extends into multiple States, the State names will be included in the title in descending order of population size within the CBSA.

#### 8. Identification of Combined Areas

Any two adjacent CBSAs will be combined if the employment interchange rate between the two areas is at least 25. The employment interchange rate between two areas is defined as the sum of the percentage of employed residents of the area with the smaller total population who work in the area with the larger total population and the percentage of employment in the area with the smaller total population that is accounted for by workers residing in the area with the larger total population.

Adjacent CBSAs that have an employment interchange rate of at least 15 and less than 25 will be combined if local opinion, as reported by the congressional delegations in both areas, favors combination. CBSAs that are combined will retain their identities as CBSAs within Combined Areas.

#### 9. Titles of Combined Areas

The title of a Combined Area will include the name of the largest principal city in each of up to three CBSAs involved in the combination in descending order of CBSA population size based on Census 2000 population.

The title also will include the name of the State in which the Combined Area extends into multiple States, the State names will be included in the title in descending order of population size within the Combined Area.

#### 10. Intercensal Update Schedule

A new CBSA will be designated intercensally if (1) a city that is outside any existing CBSA has a Census Bureau special census count of 10,000 or more population, or Census Bureau population estimates of 10,000 or more population for two consecutive years, or (2) a Census Bureau special census results in the delineation of a new UA or SC of 10,000 or more population that is outside of any existing CBSA. In the years up to 2007, outlying counties of intercensally designated CBSAs will be qualified, according to the criteria in Section 3 above, on the basis of Census 2000 commuting data.

The definitions of all existing CBSAs will be reviewed in 2008 using commuting data from the Census Bureau's American Community Survey. The central counties of CBSAs identified on the basis of a Census 2000 population count, population estimates, or a special census count will constitute the central counties for purposes of the 2008 CBSA definition review.

#### 11. General Procedures

**Local Opinion.** Local opinion is the reflection of the views of the public and is obtained through the appropriate congressional delegations. Under the CBSA standards, local opinion is sought only when two adjacent CBSAs qualify for combination based on an employment interchange rate of at least 15 and less than 25 (see Section 8). The two CBSAs will be combined only if there is evidence that local opinion in both areas favors the combination. After a decision has been made regarding the combination of CBSAs, the Office of Management and Budget will not request local opinion again on the same question until the next redefinition of CBSAs.

**New England City and Town Areas.** The New England City and Town Areas (NECTAs) provide an alternative to the county-based CBSAs in the six New England States for the convenience of data users who desire city-and-town-based areas comparable to previous MA definitions for this region.

NECTAs will be defined by applying the standards outlined in Sections 1 through 4 and 6 through 10 above for county-based CBSAs to data for cities and towns. Levels for NECTAs will not be determined. Cities and towns not included in a NECTA will be designated "Outside NECTAs."

#### H. Key Terms

(An asterisk (\*) denotes new terms proposed for the purposes of this report. Two asterisks (\*\*) denote terms whose definitions have changed for purposes of this report from previous definitions.)

**Census designated place (CDP)**—A statistical entity equivalent to an incorporated place, defined for each decennial census, consisting of a locally recognized, unincorporated concentration of population that is identified by name.

**Central city**—The largest city of a metropolitan statistical area or a consolidated metropolitan statistical area, plus additional cities that meet specified statistical criteria.

**\*\*Central county**—The county or counties of a Core-Based Statistical Area containing a substantial portion of an urbanized area or settlement cluster or

both, to and from which commuting is measured to determine qualification of outlying counties.

**\*\*Core**—A densely settled concentration of population, comprising either an urbanized area or settlement cluster (of 10,000 or more population) defined by the Census Bureau, around which a Core-Based Statistical Area is defined.

**\*Core-Based Statistical Area**—A geographic entity consisting of the county or counties containing one or more cores (urbanized areas or settlement clusters or both) that together have at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core(s) as measured through commuting.

**\*Employment interchange rate**—A measure of ties between two adjacent CBSAs used when determining whether they qualify to be combined. The employment interchange rate is the sum of the percentage of employed residents of the smaller CBSA who work in the larger CBSA and the percentage of employment in the smaller CBSA that is accounted for by workers who reside in the larger CBSA.

**Geographic building block**—The geographic unit, such as a county, that forms the basic geographic component of a statistical area.

**\*Macropolitan area**—A Core-Based Statistical Area containing one or more cores (urbanized areas or settlement clusters or both) that together have at least 50,000 population and less than 1,000,000 population, plus adjacent counties having a high degree of social and economic integration with the core(s).

**\*Megapolitan area**—A Core-Based Statistical Area containing one or more

cores (urbanized areas or settlement clusters or both) that together have at least 1,000,000 population, plus adjacent counties having a high degree of social and economic integration with the core(s).

**Metropolitan area (MA)**—A collective term, established by OMB and used for the first time in 1990, to refer to metropolitan statistical areas, consolidated metropolitan statistical areas, and primary metropolitan statistical areas.

**Metropolitan statistical area (MSA)**—A geographic entity, defined by OMB for statistical purposes, containing a core area with a large population center and adjacent communities having a high degree of social and economic integration with that center.

Qualification of an MSA requires a city with 50,000 population or more, or an urbanized area and a total population of at least 100,000 (75,000 in New England). MSAs are composed of entire counties, except in New England where the components are cities and towns.

**\*Micropolitan area**—A Core-Based Statistical Area containing one or more cores (settlement clusters of at least 10,000 population) that together have less than 50,000 population, plus adjacent counties having a high degree of social and economic integration with the core(s).

**Minor civil division (MCD)**—A type of governmental unit that is the primary legal subdivision of a county, created to govern or administer an area rather than a specific population. MCDs are recognized by the Census Bureau as the county subdivisions of 28 States and the District of Columbia.

**New England county metropolitan area (NECMA)**—A county-based

statistical area defined by OMB to provide an alternative to the city-and town-based metropolitan statistical areas and consolidated metropolitan statistical areas in New England.

**\*New England city and town area (NECTA)**—A proposed city- and town-based statistical area defined to provide an alternative to the county-based Core-Based Statistical Areas in New England.

**\*\*Outlying county**—A county that qualifies for inclusion in a Core-Based Statistical Area on the basis of commuting ties with the Core-Based Statistical Area's central county or counties.

**\*Outside core-based statistical areas**—Counties that do not qualify for inclusion in a Megapolitan, Macropolitan, or Micropolitan Area.

**\*Principal city**—The largest city of a Core-Based Statistical Area, plus additional cities that meet specified statistical criteria.

**\*Settlement cluster (SC)**—A statistical geographic area proposed for definition by the Census Bureau for Census 2000, consisting of a central place(s) and adjacent densely settled territory that together contain at least 10,000 people, generally with an overall population density of at least 1,000 people per square mile.

**Urbanized area (UA)**—A statistical geographic area defined by the Census Bureau, consisting of a central place(s) and adjacent densely settled territory that together contain at least 50,000 people, generally with an overall population density of at least 1,000 people per square mile.

[FR Doc. 99-27351 Filed 10-19-99; 8:45 am]

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# Department of Education

## List of Correspondence—Office of Special Education and Rehabilitative Services; Notice

**DEPARTMENT OF EDUCATION****List of Correspondence—Office of Special Education and Rehabilitative Services**

**AGENCY:** Department of Education.

**ACTION:** List of correspondence from October 1, 1998 through December 31, 1998.

**SUMMARY:** The Secretary is publishing the following list pursuant to section 607(d) of the Individuals with Disabilities Education Act (IDEA). Under section 607(d) of IDEA, the Secretary is required, on a quarterly basis, to publish in the **Federal Register** a list of correspondence from the Department of Education received by individuals during the previous quarter that describes the interpretations of the Department of Education of IDEA or the regulations that implement IDEA.

**FOR FURTHER INFORMATION CONTACT:** JoLeta Reynolds or Rhonda Weiss. Telephone: (202) 205-5507. Individuals who use a telecommunications device for the deaf (TDD) may call (202) 205-5465 or the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday, except Federal holidays.

Individuals with disabilities may obtain a copy of this notice in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to Katie Mincey, Director of the Alternate Formats Center. Telephone: (202) 205-8113.

**SUPPLEMENTARY INFORMATION:** The following list identifies correspondence from the Department issued between October 1, 1998 and December 31, 1998.

Included on the list are those letters that contain interpretations of the requirements of IDEA and its implementing regulations, as well as letters and other documents that the Department believes will assist the public in understanding the requirements of the law and its regulations. The date and topic addressed by a letter are identified, and summary information is also provided, as appropriate. To protect the privacy interests of the individual or individuals involved, personally identifiable information has been deleted, as appropriate.

**Part A****General Provisions***Section 607—Requirements for Prescribing Regulations*

Topic Addressed: Applicability of Regulations

Letter dated November 13, 1998 to U.S. Congresswoman Jo Ann Emerson, regarding (1) States' and school districts' obligations, pending publication of final regulations, to comply with all applicable provisions of the IDEA Amendments of 1997 and provisions of the then current regulations that were not in conflict with the IDEA Amendments of 1997, and (2) the importance of a new requirement governing the development of individualized education programs for deaf and hard of hearing children under Part B of IDEA.

**Part B****Assistance for Education of all Children With Disabilities***Section 612—State Eligibility*

Topic Addressed: Free Appropriate Public Education

Letter dated November 20, 1998 to Arizona Department of Education Superintendent Lisa Graham Keegan and Mr. Terry Stewart, Arizona Department of Corrections, regarding the responsibility of the Arizona Department of Education under Part B of IDEA, Section 504 of the Rehabilitation Act of 1973, and Title II of the Americans With Disabilities Act of 1990 to ensure the availability of a free appropriate public education to eligible youth with disabilities incarcerated in adult prisons and correctional facilities.

Letter dated December 4, 1998 to Dr. Ellen Morris Tiegerman, School for Language and Communication Development, explaining that a public agency is not obligated to reimburse for tuition costs for nondisabled preschool aged children in order to provide integrated settings to implement the individualized education programs of preschool aged children with disabilities.

Topic Addressed: Least Restrictive Environment

Letter dated October 7, 1998 to Daniel Kinley, New York State School Boards Association, regarding New York State's responsibility to ensure placements of disabled children that meet the least restrictive environment requirements of the IDEA in light of the State's funding formula that distributes State funds on

the basis of the type of setting in which a child is served.

Topic Addressed: State Education Agency General Supervisory Responsibility

Letter dated October 19, 1998 to U.S. Congressman William F. Goodling, regarding special conditions placed on Pennsylvania's Federal Fiscal Year 1998 Part B State grant concerning exercise of State Educational Agency's general supervisory responsibility, including effective monitoring of public agencies and securing correction of noncompliance.

Topic Addressed: Children Enrolled by Their Parents in Private Schools

Letter dated October 20, 1998, to U.S. Congressman Robert T. Matsui, regarding the extent of public agencies' obligations to provide special education and related services under Part B of IDEA to children with disabilities enrolled by their parents in private schools.

Letter dated November 13, 1998 to Helen Walter, Advocate for Hard of Hearing People, regarding limited scope of due process rights for parents who enroll their children in private schools.

*Section 613—Local Educational Agency Eligibility*

Topic Addressed: Treatment of Charter Schools and Their Students

Letter dated October 8, 1998 to Wisconsin Department of Public Instruction State Superintendent John T. Benson, regarding (1) the Department's deference to, and agreement with, the State's interpretation that schools chartered by the City of Milwaukee, like all other charter schools in the State, are public schools, (2) the obligation of charter schools to ensure the provision of a free appropriate public education to children with disabilities and the obligation of the State to ensure compliance with the IDEA, and (3) consequences of noncompliance with related Federal civil rights laws.

Letter dated November 4, 1999 to B. J. Stockton, Missouri Department of Elementary and Secondary Education, regarding the Department's view that charter schools generally should be presumed to be public schools which are subject to requirements regarding a free appropriate public education in Part B of IDEA, and clarifying that in order to be eligible for funds under the Federal Public Charter Schools Program, the participating charter schools must be public schools that comply with Part B of IDEA, Section 504 of the Rehabilitation Act of 1973, and Title II

of the Americans With Disabilities Act of 1990.

Memorandum dated August 10, 1998, to Chief State School Officers from former Assistant Secretary for the Office of Elementary and Secondary Education Gerald N. Tirozzi, regarding allocation of state-administered federal education funds to public charter schools.

*Section 614—Evaluations, Eligibility Determinations, Individualized Education Programs, and Educational Placements*

Topic Addressed: Evaluations and Reevaluations

Letter dated November 18, 1998 to individual, (personally identifiable information redacted), regarding specific provisions in the IDEA Amendments of 1997 that reduce paperwork requirements, as well as the importance of ensuring local flexibility in the implementation of the IDEA Amendments of 1997.

*Section 615—Procedural Safeguards*

Topic Addressed: Timelines for Appeals

Letter dated November 13, 1998 to individual, (personally identifiable information redacted), regarding absence of timelines in Part B of IDEA for appealing due process hearing decisions or bringing of civil actions.

Topic Addressed: Student Discipline

Letter dated October 20, 1998 to U.S. Senator Ted Stevens, regarding options available to school authorities under the Individuals With Disabilities Education Act Amendments of 1997 in disciplining students with disabilities.

Letter dated November 18, 1998 to South Carolina State Representative J. Roland Smith, regarding circumstances under which students with disabilities can be subjected to more than one removal from school for ten consecutive school days or less in the same school year.

Letter dated November 5, 1998, to Mr. Dick Buscher, Paradise Valley Unified School District, regarding options available to school authorities in disciplining students with disabilities and clarifying that students with

disabilities are not automatically exempt from disciplinary sanctions because of their status as disabled students.

Letter dated October 20, 1998 to individual, (personally identifiable information redacted), letter dated December 8, 1998 to individual, (personally identifiable information redacted), and letter dated December 8, 1998 to individual, (personally identifiable information redacted), regarding options available to school authorities in disciplining students with disabilities.

Topic Addressed: Transfer of Rights

Letter dated December 21, 1998 to individual, (personally identifiable information redacted), regarding the special rule under which a State is required to appoint the parent or another appropriate individual to represent the educational interests of the student throughout his or her eligibility under the Act if the State has a mechanism to, and determines that, an individual with a disability who has reached the age of majority under State law and has not been declared incompetent, but cannot provide informed consent with respect to his or her educational program.

**Part C**

**Infants and Toddlers With Disabilities (Previously Part H)**

*Sections 631–641*

Topic Addressed: Implementation of a Statewide System

Letter dated December 16, 1998, to Mary Miller, Illinois Bureau of Part C/ Early Intervention, regarding the obligation to ensure that early intervention services are available to all eligible infants and toddlers and their families.

Topic Addressed: Evaluations

Letter dated December 30, 1998, to Ms. Ginny Duncan, Parent Education Network, regarding the role of a service coordinator on the Multidisciplinary Evaluation Team and the exclusion of

service providers from initial evaluations.

Topic Addressed: State Interagency Coordinating Council

Letter dated October 5, 1998, to Ms. Mary Alice Leonard-Heath and Mr. Wayne Fox, Co-Chairs of the Vermont Interagency Coordinating Council, regarding ICC membership of a representative of a State lead agency.

Topic Addressed: Administration of Part C Funds

OSEP Memorandum dated December 30, 1998, to Lead Agency Directors and Part C Coordinators, regarding Restricted Indirect Cost Rate for Part C of the Individuals with Disabilities Education Act.

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(Catalog of Federal Domestic Assistance Number 84.027, Assistance to States for Education of Children with Disabilities)

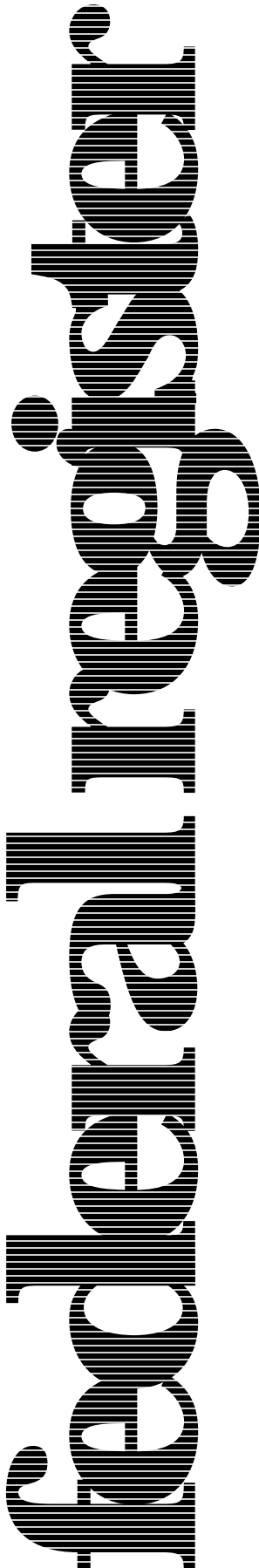
Dated: October 13, 1999.

**Judith E. Heumann,**

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

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Wednesday  
October 20, 1999

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**Part VI**

**Department of  
Health and Human  
Services**

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**Health Resources and Services  
Administration**

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**42 CFR Part 121  
Organ Procurement and Transplantation  
Network; Final Rule**



# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Resources and Services Administration

### 42 CFR Part 121

### Organ Procurement and Transplantation Network

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** This document sets forth improvements to the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), published in 1998. It reflects the advice of a panel convened by the National Academy of Science's Institute of Medicine, as called for in the Department's appropriation act for 1999. It also reflects comments on the 1998 rule and consultation with representatives of the organ transplantation community, as recommended in the same legislation; and it summarizes new transplant data developed in the period since enactment of the appropriations act.

**DATES:** The final rule published on April 2, 1998, 63 FR 16296, adding 42 CFR part 121 with an effective date of October 1, 1998, as amended on July 1, 1998, 63 FR 35847, did not take effect under section 213(a) within Public Law 105-277, 112 Stat. 2681, 2681-359 through 2681-360, approved October 21, 1998. The April 2, 1998 rule as amended by this document, is effective on November 19, 1999.

**FOR FURTHER INFORMATION CONTACT:** D.W. Chen, M.D., M.P.H., Director, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Room 7C-22, Rockville, MD 20857, telephone 301-443-7577.

**SUPPLEMENTARY INFORMATION:** On April 2, 1998, the Department of Health and Human Services (HHS) published in the **Federal Register** a final rule pertaining to the operation of the Organ Procurement and Transplantation Network (63 FR 16296). In accordance with the National Organ Transplant Act (NOTA) of 1984, as amended, the purpose of the final rule is to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation. Toward this end, the final rule establishes performance goals intended to bring about:

(1) Standardized criteria for placing patients on transplant waiting lists, (2) standardized criteria for defining a

patient's medical status, and (3) allocation policies that make most effective use of organs, especially by making them available whenever feasible to the most medically urgent patients who are appropriate candidates for transplantation. The final rule also sets standards for availability of organ transplantation data, and it addresses the governing structure of the OPTN. No provision of the final rule is intended to interfere with the discretion of individual health professionals and patients in medical decision-making, and the rule looks to the OPTN to design organ allocation policies. At the same time, the rule defines the policy oversight responsibilities of the Secretary of HHS. In concert with efforts to encourage organ donation, the final rule is intended to help make best use of the limited number of organs available for transplantation.

The final rule invited further comments, which have been received and reviewed. In addition, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for 1999 delayed implementation of the final rule until October 21, 1999. (This Omnibus Act, Public Law 105-277, at section 101(f) of Division A, enacted the Department of Labor, HHS, and Education, and Related Agencies Appropriations Act, 1999. Within the latter act, section 213 included provisions related to the final OPTN rule, 112 Stat. 2681, 2681-359 through 2681-360. Hereafter, for ease of reference, we will refer to section 213 of the Appropriation Act, or simply section 213.) Section 213 called for independent review through the National Academy of Science's Institute of Medicine. It also suggested development of improved information on the effectiveness of the transplantation system, including center-specific information if possible. Finally, it suggested further discussions between HHS and representatives of the transplant community. Each of these areas has been addressed.

### I. Background

#### A. Legislative and Regulatory History

Legislative and regulatory history are outlined in the preamble to the April 2, 1998, final rule. In addition to the underlying statute (sections 371-376 of the Public Health Service Act, as enacted by the National Organ Transplant Act of 1984, and as subsequently amended), of particular importance is section 1138 of the Social Security Act, enacted in 1986. This legislation requires hospitals that perform organ transplants to be

members of, and abide by the rules and requirements of, the OPTN as a condition for participation in the Medicare and Medicaid programs. This provision subjects a transplant hospital's entire Medicare and Medicaid participation, and thus in reality its economic survival, to OPTN policy and enforcement. A similar provision in section 1138 affects funding under Medicare and Medicaid for organ procurement organizations (OPOs). But authority for establishing conditions of participation in Medicare and Medicaid resides with the Secretary and cannot be exercised by another party without either oversight authority or delegation. Thus, review and oversight authority of OPTN policies by the Secretary of HHS is made even more necessary by section 1138. A **Federal Register** notice published on December 18, 1989 (54 FR 51802) addressed this need by stating that no OPTN policies are legally binding "rules or requirements" of the OPTN for purposes of section 1138, unless they have been approved by the Secretary. The final rule published April 2, 1998, defines the structure for such review and approval, thus setting the stage for OPTN "rules or requirements" that would be enforceable on transplant hospitals and OPOs under section 1138.

In October 1998, section 213 of the Appropriation Act delayed implementation of the final rule to October 21, 1999. Section 213 directed that the Institute of Medicine conduct a review of the current policies of the OPTN and the final rule. Section 213 also suggested that the Secretary "may conduct a series of discussions with the OPTN in order to resolve issues raised by the final rule." In addition, section 213 indicated a need for improved availability of data on transplantation and transplant center performance.

#### B. Institute of Medicine Report

The Institute of Medicine (IOM) issued its report, *Organ Procurement and Transplantation*, on July 22, 1999. The report included five major recommendations. The Department has relied heavily on the guidance in the IOM report in reviewing the provisions of its final rule. In general, the IOM report validates the concerns that gave rise to the final rule and the approaches taken in the rule:

Recommendation 1: Establish Organ Allocation Areas for Livers. The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas (OAAs) for livers—each serving a population base of at least 9 million people (unless such an area would exceed the limits of acceptable cold ischemic time).

OAA's should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities.

Recommendation 2: Discontinue Use of Waiting Time as an Allocation Criterion for [Liver Transplant] Patients in Statuses 2B and 3. The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time relatively misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for status 2B and 3 patients. An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times.

Recommendation 3: Exercise Federal Oversight. The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the final rule, to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

Recommendation 4: Establish Independent Scientific Review. The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.

Recommendation 5: Improve Data Collection and Dissemination. Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely available to independent investigators and scientific reviewers in a timely manner. The Department of Health and Human Services should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN.

In addition, the General Accounting Office (GAO) made findings in two other areas required by section 213: the possibility of legal liability of OPTN members arising from their peer review activities and the confidentiality of information. Regarding liability, the General Counsel of the GAO found no apparent conflict between the final rule and State laws governing peer review. Regarding confidentiality, the General Counsel found that the Secretary of HHS has authority under the final rule to decide that the public interest in disclosure of information about organ

transplants outweighs the interest in confidentiality.

### C. Discussions With the Transplant Community

Representatives of HHS met with members of the transplant community on numerous occasions in the period immediately following publication of the final rule. Since enactment of section 213, representatives of HHS have met on 11 separate occasions with representatives of 11 transplant organizations: United Network for Organ Sharing (UNOS, the current OPTN contractor), Transplant Recipients International Organization, American Liver Foundation, National Transplant Action Committee, National Minority Organ and Tissue Transplant Education Program, National Kidney Foundation, Patient Access to Transplantation Coalition, American Society of Transplantation, American Society of Transplant Surgeons, North American Transplant Coordinators Organization, and the American Nephrology Nurses Association. On September 15, 1999, an additional meeting with representation invited from all of these organizations took place to discuss together issues that had been surfaced.

### Clarifications

HHS is further clarifying these issues with this publication:

- *"National" lists:* The final rule does not require single national lists for allocation of organs, beyond the national registry lists already utilized by the OPTN. As underscored by the IOM recommendations, it is the Department's goal to achieve sharing of organs broad enough to achieve medically effective results for patients, especially by providing organs for patients with greatest medical urgency who are appropriate candidates for transplantation. When using the terms "greatest medical urgency," or "most medically urgent," the Department is referring to transplanting those patients whose medical condition, in the judgment of their physicians, makes them suitable candidates for transplantation. The final rule directs the OPTN to overcome as much as possible arbitrary geographic barriers to allocation that restrict the allocation of organs to patients with greatest medical urgency who are appropriate candidates for transplantation and that are not based on medical criteria. Broader sharing was an essential element of the IOM's findings.

- *Most Medically Urgent Patients:* The final rule follows, and intends to expand, existing policy in serving most

medically urgent patients first, again, referring to patients who are suitable candidates for transplantation. It is not the Department's intention to require transplantation of patients too ill to benefit; the final rule specifically prohibits policies that might result in such futile transplantations and organ wastage. Providing available organs to patients with greatest medical urgency who are appropriate candidates for transplantation is already the policy of the OPTN within allocation areas. Transplant priority for patients with greatest medical urgency, whenever they are medically suitable, follows the tenets of medical practice generally and is already accepted throughout the transplant community and general public.

- *Medical Factors Affecting Organ Movement:* The final rule fully recognizes limitations on movement of organs resulting from medical factors, especially limits of ischemic time. As recommended by the IOM report, and as intended by the 1998 final rule, sharing of organs should be broad enough to enable medically effective use of organs, especially to enable organs to reach the most medically urgent patients, but ischemic time limits and any other medical factors affecting the viability of the organ must be considered in designing allocation policies.

- *Small and Medium Sized Transplant Centers:* The Department does not expect the final rule to cause the closure of small or medium sized transplant centers or otherwise diminish access to transplantation for certain populations, including those living in rural areas. The IOM report did not find evidence that the rule would have such effects; and a report by the HHS Office of Inspector General ("Fostering Equity in Patient Access to Transplantation: Local Access to Liver Transplantation," dated August 1999) concluded that geographic distribution of liver transplant centers is unlikely to change as a result of national policies on organ allocation. The Department is concerned that patient access to transplant services not be adversely affected by closure of centers that are providing quality care, including small and medium sized centers. Thus, the amendments below include provision for monitoring any effects of policy changes on small and medium sized centers. However, HHS and the OPTN should work together to ensure that all transplant programs, regardless of volume, are providing quality care to candidates and recipients.

- *Designated Transplant Program Requirements:* The final rule carries forward the policies in the proposed

rule that provided separate staffing and organizational "designated transplant program" requirements for non-Medicare participating transplant programs and those that are certified as Medicare approved transplant programs. The Department has received comments similar to those submitted in response to the proposed rule, suggesting that uniform standards be applied for designation status. The Department continues to have no objection to this suggestion in principle, but believes that the OPTN should submit such standards for the Secretary's consideration as possible changes to the Medicare conditions for coverage of organ transplants, which currently contain similar requirements.

#### Secretarial Oversight and Enforceability of OPTN Policies

Virtually all commenters agreed that HHS should exercise an oversight role over OPTN policies, although there were different views among the participants as to how such oversight should be carried out. Exercise of HHS oversight was also one of the five primary recommendations of the IOM report. Further, as explained in "Legislative and Regulatory History" above, section 1138 of the Social Security Act elevates OPTN membership and policies to the status of requirements for participation in Medicare and Medicaid for transplant hospitals and OPOs, thus necessitating Secretarial review and oversight authority over those policies. The final rule provides the framework for such oversight as well as the framework for creating a body of enforceable OPTN policies.

An additional recommendation by the IOM was establishment of an independent scientific review board "for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." In response to this recommendation in the IOM report as well as comments received, the Department intends to create such an advisory board, the Advisory Committee on Organ Transplantation. The Department intends to implement the IOM's recommendations that this Committee have several key responsibilities. As recommended by the IOM, the Committee will provide "timely, nonpartisan review" to "assist the Secretary in managing the system in a manner that best serves the public interest." It will also, as recommended by the IOM, "help provide objective information and advice for future

directions for the [organ transplantation] system." It would also, as recommended by the IOM, "help insure that policies and procedures are evidence-based and guided by the best available scientific and medical precepts." In order that the Committee fulfill this latter responsibility, § 121.4 (b)(2) and (d) have been revised to reflect this role.

When the OPTN proposes enforceable policies, the Secretary will ask the Committee for its views on the proposals when the proposals are published in the **Federal Register** for public comment. The Committee's views, public comments, and the Department's views will then serve as the basis for discussions with the OPTN. If, after these discussions, the Secretary wishes to direct that the OPTN revise its proposals, the OPTN will have the opportunity to suggest revisions. If the Secretary does not agree with the OPTN's revised approach (or if it does not respond in a timely manner), the Secretary may require the OPTN to take other appropriate actions. However, the Secretary will ask the Committee for its views on the specific proposed actions before transmitting them to the OPTN. A similar approach may also be used should the Secretary review other OPTN policies, or elect to evaluate critical comments received by the Secretary relating to the manner in which the OPTN is carrying out its duties.

It is not the desire, nor is it the intention, of the Department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety, and urgency that must be judged by transplant professionals. The Advisory Committee will greatly assist the Secretary with respect to the medical and scientific components of OPTN policies. The medical community has substantial contributions to make within the deliberative process for developing OPTN policies, as well as in individual decisions involved in clinical transplantation practice.

The rule also has been revised to emphasize that the Secretary's review is intended to ensure consistency between OPTN policies and the National Organ Transplant Act and this regulation. This revision is intended to emphasize, as the IOM did in its report, that the Secretary's oversight will further the public interest, a role assigned to the Department by the National Organ Transplant Act and articulated in this regulation.

#### OPTN Board Composition

Participants expressed a variety of views on requirements concerning the

composition of the OPTN Board of Directors. Some participants believed that the rule should require, not merely authorize, the Board to include at least 50 percent representation of transplant physicians and transplant surgeons, to ensure a preponderance of medical expertise. Others suggested more even division of representation among transplant physicians and transplant surgeons, other non-physician transplant professionals, and candidates, recipients, donors, their families, and the general public. Concern was also raised that a combination of percentage representation requirements with specific categorical representation requirements would make the Board so large as to be unwieldy, if the Board chose to allow 50 percent representation of transplant physicians and surgeons. The Department has reorganized and revised the Board and Executive Committee composition provisions to strengthen the role of transplant physicians and surgeons on the Board, consistent with the rule's thrust that allocation policy (one of the OPTN's most important responsibilities) be based on objective and measurable medical criteria and sound medical judgment, to strengthen the role of transplant candidates, recipients, donors, and their families on the Board and its Executive Committee, and to provide the OPTN greater flexibility in determining the appropriate size for the Board. This document includes amendments that identify categories of membership, but do not require a specific number of members from each category. This amendment requires approximately 50 percent transplant physician or transplant surgeon membership, instead of no more than 50 percent, and specifies at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

We have retained the provision designed to avoid even an appearance of a conflict of interest by requiring that transplant candidates, recipients, donors and family members on the Board not have an "employment or similar relationship" with certain entities and individuals involved in transplantation. However, we received comments suggesting that such individuals may have exceptional commitment or knowledge and should not be automatically disqualified from Board membership, and that, in any event, the Board should have additional flexibility in this area. We have revised this provision to authorize the Board to waive this requirement for up to half of

these members. We expect the Board to use this flexibility consistent with the rule's goal of broad involvement of patients, recipients, donors, families and the public in the formulation of transplant policy.

#### Broader Geographic Sharing of Organs

The final rule's emphasis on broader sharing of organs is being clarified through this document. Establishment of liver allocation areas broad enough to provide for medically effective allocation of organs was the leading recommendation of the IOM report. Some commenters expressed concern about the need for the transplant system to use standard criteria for listing patients and assigning their urgency status, and likewise the need for enforcement mechanisms to ensure that medically urgent patients who are appropriate candidates for transplantation are not disadvantaged through misuse of listing criteria or priority rankings. The final rule calls on the OPTN to develop such standard criteria, and to monitor compliance with them, prospectively if appropriate. Further, by establishing a framework for Secretarial review and approval of OPTN policies, as well as review and evaluation procedures for the OPTN, the rule provides a foundation for enforcement of these standard criteria.

#### Frequency and Timeliness of Data

Most participants expressed support for enhanced frequency and timeliness of data. Likewise, the IOM report strongly urged improvements in data collection and dissemination, both for physician and patient information and to provide outcome data that may improve understanding of best medical practices. As OPTN contractor, UNOS expressed concern about its ability to meet the frequency requirements in the April 2 final rule. The Department has decided to retain the 6 month data presentation requirement. The Department recognizes that UNOS' concerns stem in part from its belief that certain types of data may not need to be updated as frequently as others. Therefore, the Department has added a provision that would permit longer intervals for certain data.

The Department recognizes the progress that UNOS has made in increasing the availability of program-specific information for use by patients, families, physicians, and payors. To respond to the contractor's concerns regarding its ability to meet the frequency of the reporting requirement in the final rule, HHS will not require the submission of the first program-specific report under § 121.11(b)(1)(iv)

until June 30, 2000. This will allow OPTN member organizations adequate time to become fully Y2K compliant and ensure that all data submitted to the OPTN is done so electronically, and will enable the contractor to meet the Department's and the IOM's expectations that information be more timely and accessible.

#### Use of Waiting Time

In general, the IOM found the emphasis on cumulative waiting times to be inappropriate as a measure of equity in the transplant system and as a criterion for allocation for less medically urgent patients, pointing instead toward "more meaningful indicators of equitable access" such as "status-specific rates of pretransplantation mortality and transplantation." The IOM report indicated, however, that the use of "waiting times in status" for the most medically urgent liver transplant patients (those in status 1 and 2A) was "an appropriate criterion, along with necessary medical criteria." For less medically urgent patients (statuses 2B and 3), the IOM recommended that the OPTN discontinue use of waiting time as an allocation criterion and instead develop "an appropriate medical triage system . . . to ensure equitable allocation of organs to patients in these categories." HHS generally agrees with these findings, although the Department believes that waiting time in status (unlike cumulative waiting time) can be one among several useful criteria in assessing variability in results for patients at different transplant centers. To date, waiting times have been used in examining the performance of the transplant system in part because waiting times are used by the OPTN as an allocation criterion, and in part due to lack of better measures. It is for these reasons that reducing any variations in "waiting time in status," especially for the most medically urgent patients, was included as a performance measure in the final rule published April 2. In addition, the IOM recommendation points again to the need for better data to provide alternatives to waiting time as a performance measure. Based on the IOM's recommendations and comments from the transplant community, the Department has made additional refinements to the rule's discussion of waiting times.

The Department's approach in this section follows the recommendations of the IOM and responds to issues raised by commenters. First, the Department agrees with the IOM recommendations that "overall" waiting times are an inappropriate measure. The concept of

using "waiting time in status" is, however, permitted as a factor in allocation policy.

Second, § 121.8(b)(4) requires the OPTN to use performance indicators to assess transplant program performance and to seek to reduce the variations among transplant programs with respect to selected performance indicators. This "performance indicator" approach is consistent with the IOM's recommendation that data be used to assess transplant program performance. Among the alternatives available to the OPTN is the performance indicator "waiting time in status." Consistent with the IOM's approach, if the OPTN retains waiting time in status for allocation purposes for medically urgent categories similar to current Status 1 and 2A in its revised liver allocation policies, the Department would expect the OPTN to use waiting time in status as a performance indicator for liver patients, along with necessary medical criteria.

Regarding the general approach of reducing variations among transplant programs with respect to selected performance indicators, we also expect the OPTN to work towards improving, where possible, the outcomes under these indicators. For example, if the OPTN used the performance indicator pretransplantation mortality rates for liver patients by medical status, as recommended by the IOM, then the Department would expect the OPTN to seek to reduce the variations in this performance indicator by improving pre-transplant survival at programs where it fell significantly below the national rates.

We also note that, although § 121.8(b)(2) requires that the medical characteristics of patients within each category be as similar as possible, the IOM observed that the current liver status categories 2B and 3 were heterogeneous. As a result, some patients in these categories need life-saving transplants sooner than others. The other patients, often with longer waiting times, can, nevertheless, wait longer periods of time without increased risk of death. Therefore, the IOM concluded that the OPTN should not use waiting times as a criterion for patients in these categories. Some commenters, however, suggested that the OPTN would have difficulty further refining its existing status categories. Commenters also requested that the OPTN be allowed to continue to use waiting times in some fashion for these patients. This rule provides the OPTN flexibility to continue to use waiting times for patients in these categories but would require that such use not

override medical urgency considerations.

However, the Department expects, as the IOM concluded, that broader sharing of organs should occur for all patients and that organs will go to more medically urgent patients who are appropriate candidates for transplants before being offered to patients whose condition permits them to wait longer for a transplant.

#### OPTN Review of Member Compliance With Final Rule Requirements and Mandatory OPTN Policies

Many members of the transplant community expressed concern about how best to promote compliance with OPTN policies. Section 121.8(a)(7) has been added to emphasize that the OPTN should especially promote compliance with approved allocation policies through prospective and retrospective reviews of programs' compliance with allocation policies. In addition, the OPTN is required by § 121.10 to conduct reviews and evaluations of each OPTN member's compliance with these rules and approved OPTN policies. Thus, the OPTN is required to implement a review process to ensure that individuals receiving transplants are accurately listed and in proper classification categories to receive organs. Currently, UNOS liver and thoracic Regional Review Boards (RRBs) provide retrospective review of designation of status 1 and 2A patients for livers and 1A patients for hearts. The Department will explore with the OPTN contractor issues related to the conduct of prospective and/or retrospective reviews of all listings and changes in status categories to assure that programs are making appropriate classification determinations. Reviews, prospective and retrospective, might be performed by existing OPTN RRBs. In addition, the Secretary may ask independent third parties, such as the Joint Commission on the Accreditation of Health Organizations (JCAHO), or Utilization and Quality Control Peer Review Organizations (PROs) established under Part B of title XI of the Social Security Act, to monitor the OPTN enforcement system by independently conducting audits of the work of the RRBs.

#### Incentives for High Performing OPOs

Concern has been expressed that, by emphasizing broader sharing of organs, the final rule might bring about reduced organ donation. The Department disagrees, and the IOM report found some evidence that, where broader sharing is currently occurring, donations have increased. In response to these concerns, however, HHS has

considered the possibility that positive rewards might be offered for high performing OPOs, to add to incentives for organ donation. The Department believes that high performance by OPOs should be rewarded in a way that does not disadvantage patients by compromising one of the fundamental objectives that the final rule is trying to achieve—namely broader sharing of organs. Therefore, the Department encourages the OPTN to develop and recommend to the Secretary policy incentives to reward high-performing OPOs. In addition, in response to longer-standing concerns, HHS' Health Care Financing Administration (HCFA) is reviewing the way it currently measures OPO performance.

#### Policies to Address Socioeconomic Barriers

Some in the transplant community have expressed concern that the final rule would require transplant hospitals to make their own financial resources available to pay for transplant and follow-up care for patients unable to pay. However, this was not the intention of the April 2 final rule. The rule calls on the OPTN Board of Directors to recommend policies that would reduce inequities in access resulting from socioeconomic status and ensure that the registration fee itself does not represent a barrier to transplantation.

#### Registration Fees

One commenter objected to Secretarial review of that portion of registration fees paid by OPTN members (and indirectly by patients and their insurers) that represents expenditures by the contractor that are not directly related to the tasks performed under the contracts with HHS. The final rule specifies that the Secretary has oversight of that portion of the registration fee directly related to operation of the OPTN.

#### Health Resources and Services Administration (HRSA)–HCFA Cooperation

A commenter noted the need for increased coordination between HRSA and HCFA on transplantation issues within their respective areas of responsibility. HRSA and HCFA have pursued several cooperative efforts to achieve increased organ donation, a goal of the Administration's National Organ and Tissue Donation Initiative, which was launched in December 1997. On June 22, 1998, HCFA published a final rule (42 CFR part 482) regarding Medicare Hospital Conditions of Participation, which requires hospitals to refer all deaths and imminent deaths

to local OPOs and conduct donation request training programs for appropriate staff representatives. In 1999, HRSA and HCFA jointly sponsored projects to encourage collaboration between hospitals and OPOs in effectively implementing this regulation. HCFA's responsibility for OPO performance standard establishment, certification and recertification of OPOs, and OPO waiver request review involves close cooperation with HRSA to identify practices most likely to benefit donor families and transplant patients, and that impact current organ allocation policy. In addition, HCFA and HRSA are working together to enhance and better coordinate collection, reporting, and analysis of organ procurement and transplant data in an effort to assure optimum performance of the OPTN.

#### D. Data

Section 213 called for "timely and accurate program-specific information on the performance of transplant programs." The IOM report, in reviewing 68,000 medical records, made a significant contribution in the data area, although the report also cited the paucity of data available and recommended improved data collection and dissemination. In addition, UNOS recently has added Internet-based capability, both for providing information to physicians and the public and for collecting data from its members.

Finally, HHS has completed new transplant program-specific analyses that show varying outcomes for patients among different transplant hospitals. Department staff analyzed OPTN patient outcome data for liver and heart transplants with respect to three critical issues: (1) The likelihood that, having been listed as a transplant candidate, a patient will receive an organ within one year; (2) the likelihood that a patient will die within one year of listing while awaiting transplantation; and, (3) the likelihood that a patient will still be alive one year after listing, irrespective of whether he or she underwent a transplant procedure. After risk adjustment (*i.e.*, adjustment for differences in the mix of patients' health status from program to program), the analyses revealed substantial differences in outcomes from one transplant program to another. The principal findings for liver transplants illustrate that:

- Ten percent of the programs have a standardized risk-adjusted rate of transplantation within one year of listing of 71 percent or more; whereas,

for another ten percent of the programs, the rate is 25 percent or less;

- The likelihood of dying within one year of listing while awaiting a transplant ranges from less than 8 percent to more than 22 percent; and
- The likelihood of surviving one year after listing as a transplant candidate or a recipient ranges from approximately 65 percent to almost 86 percent.

The analogous values for heart transplants are 72 and 36 percent (transplantation within one year of listing), 9 and 23 percent (death within one year of listing while awaiting a transplant), 67 and 84 percent (survival for one year after listing irrespective of whether transplanted or not).

In the course of performing these analyses, Department staff identified gaps in the data currently collected by the Scientific Registry—*e.g.*, additional clinical details about patients' conditions at the time of listing (which could improve risk adjustment) and additional data on clinical complications (which could help in assessing quality of life following transplantation). The Department has provided these analyses to UNOS and has encouraged it, in its management of the OPTN and its operation of the Scientific Registry, to broaden the scope of data collection and make increased use of program-specific performance analyses. The analyses are included in the U.S. Department of Health and Human Services 1999 Report to Congress on the Scientific and Clinical Status of Organ Transplantation.

## II. Public Comments

Between April 2 and September 16, 1998, we received a total of approximately 2,500 comments on the final rule. (Letters with petitions or with form letters attached were counted as one comment. HHS received a total of approximately 20,000 form letters.) The majority of the comments reflected issues addressed in "Clarifications" above. This document includes changes intended to make these issues clear. Other issues raised by commenters were discussed in the meetings conducted this year pursuant to section 213 of the Appropriation Act, and they are also outlined above.

## III. Changes in the Regulatory Text

As a result of the comments received, the Department has made several modifications to the final rule published on April 2, 1998. Some changes have been made to clarify the regulatory language. Other revisions to the regulatory text add provisions or modify

requirements from the previously published final rule.

### 1. Definition of Organ

The Department has deleted bone marrow from the definition of organ in § 121.2 because it falls within the scope of a different statutory authority. Although the NOTA refers to bone marrow for purposes of the Scientific Registry, subsequent legislation established a separate program to address "unrelated" bone marrow transplants. A commenter recommended that the definition be expanded to include intestine, stomach, or a collection of human cells that perform a vital function of an organ, including any organ containing vasculature that carries blood after transplantation. In the Preamble to the 1998 rule, the Department stated: "The inclusion of other organs, such as the stomach and intestines, not only would have an impact on other requirements in these regulations such as the development of allocation policies, certification of designated transplant programs, and establishment of training requirements but also would affect OPO requirements to procure these organs in accordance with HCFA rules. Thus, the Department believes it would be premature for this rule to specify other organs in addition to those already named. Instead, the Department will direct the OPTN contractor to consider which organs or parts of organs, if any, should be subject to OPTN policies, and to submit recommendations to the Secretary." The Department's position on this issue remains unchanged.

### 2. National List

The term "national list" has been replaced with "waiting list" in § 121.2, and throughout the final rule. The term "national list" was incorporated into the regulation to reflect statutory language in section 372 of the Public Health Service (PHS) Act, 42 U.S.C. 274, which requires the OPTN to "establish a national list of individuals who need organs." Current OPTN allocation convention derives subordinate lists from a single database and current OPTN policy allocates zero-antigen mismatched kidneys nationally, due to scientifically demonstrated improvements in patient and graft survival resulting from this policy. Furthermore, ischemic times and patient outcomes make such an approach appropriate in the case of zero-antigen mismatched kidneys. If supported by scientific evidence, the Department has no objection to this approach.

### 3. Composition of OPTN Board of Directors

The Department wishes to ensure adequate patient, donor and family representation on the OPTN Board of Directors, while giving the OPTN sufficient flexibility to constitute a balanced and effective Board. Thus the Department has included a requirement under § 121.3(a) that the Board of Directors shall include at least 25 percent transplant candidates, transplant recipients, organ donors, and family members. In response to comments, the Department also has revised § 121.3(a)(1) to enable the OPTN to govern itself with greater flexibility than was provided by the 1998 rule. The revised language maintains the requirement that the Board of Directors include representatives of OPOs, transplant centers, voluntary health associations, transplant coordinators, histocompatibility experts, other non-physician transplant professionals, and the general public, but does not mandate a specific number of members from each category. The Secretary believes that the less prescriptive language in this revision will better allow the OPTN itself to determine the appropriate size of, and representation on, its Board of Directors, while achieving a balance among physician, patient, donor, family and other representatives.

Section 121.3(a)(2) has been revised. That paragraph prohibited those Board members who were identified as transplant recipients, transplant candidates, organ donors, family members, or members of the general public to be employees of, or have similar relationships with, specified categories of institutional members required to be on the Board. The revised paragraph is more flexible, as described more fully above.

As discussed above, § 121.3(a) has been revised to require that approximately 50 percent of the Board members be transplant surgeons or transplant physicians, rather than the language of the April 2, 1998, rule requiring no more than 50 percent, and that at least 25 percent of its members be transplant candidates, transplant recipients, organ donors, and family members. The comparable requirements for the Executive Committee of the Board have been similarly revised. Transplant physicians or transplant surgeons elected to the Board or Executive Committee under other categories must be counted toward the requirements of these paragraphs of the final rule.

Furthermore, the requirement for a two year term for Board members in former § 121.3(a)(4) has been deleted. Board members have diverse backgrounds and will require different periods of time to become familiar with the complex issues coming before the Board. Thus, we believe that it is appropriate for the OPTN to determine for itself the length of the term for Board members, subject to Departmental review.

#### 4. Socioeconomic Issues

As articulated in the April 2, 1998, rule, the Department is concerned that all patients in the country have access to transplantation and encourages the OPTN to work toward this goal. Several members of the transplant community, however, commented that the provisions of § 121.4 addressing socioeconomic issues would require transplant hospitals to make their own financial resources available to pay for transplantation and follow-up care for patients unable to pay. In response to these comments, the Department has revised this section to specify that paragraph (a)(3)(i) refers only to the registration fee and has revised paragraph (a)(3)(ii) to clarify that resources for patients unable to pay should be sought from all available sources.

#### 5. Secretarial Review of OPTN Policies

In response to comments asking which OPTN policies are to be submitted to the Secretary, the Department has modified the language of § 121.4(b)(2) to provide that the Board of Directors is required to provide the Secretary with proposed policies that the OPTN recommends be enforceable under § 121.10 (including allocation policies) and others as specified by the Secretary. As discussed above, the rule has been revised to adopt the IOM's recommendation that the Advisory Committee assist the Secretary in reviewing OPTN policies and practices as well as to indicate the purposes of the Secretary's review.

The timing requirement has also been changed from 30 days to 60 days before implementation of the proposed policy to provide a more realistic estimate of the time required for review by the Advisory Committee and the public, should such review be necessary.

#### 6. Registration Fee

One commenter objected to Secretarial review of the patient registration fee, maintaining that this fee is paid voluntarily by OPTN members for the services provided to them by the contractor. The Department agrees that

a portion of the current fee represents a voluntary payment by OPTN members to the contractor for services outside the direct operation of the OPTN on behalf of patients, while another portion represents the payment provided by patients and their insurers for the operation of the OPTN system itself. Consequently, the Department has modified the language of § 121.5(c) to indicate that the portion of the registration fee subject to Secretarial oversight is that portion directly related to operation of the OPTN; any other fee may only be charged on a voluntary basis to OPTN members. In this regard, the Department would interpret the "reasonable costs" for operating the OPTN to include additional costs of compliance under § 121.8(a)(7) and reviews and enforcement under § 121.10.

#### 7. Human Immunodeficiency Virus (HIV)

Commenters suggested revising the language of § 121.6(b) to authorize transplantation of organs from HIV positive donors to HIV positive recipients. The Department has revised § 121.6(b) to reflect the language of the statute. We note, however, that HCFA regulations governing OPOs, at 42 CFR 486.306(q), require OPOs to screen donors to "[e]nsure that appropriate donor screening and infection tests, consistent with the OPTN standards and the CDC [Centers for Disease Control and Prevention] guidelines \* \* \* are performed \* \* \* to prevent the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome." The OPO regulations require that OPO donor screening meet the two thresholds of the OPTN standards as well as the CDC guidelines. OPOs must comply with the CDC "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs" as appended to the regulations for OPOs (see 42 CFR part 486, Subpart G, Appendix A). As a result, the OPO regulations will still preclude acquisition of an organ from an HIV-positive donor for transplantation. The OPTN may propose standards permitting such transplantation to the Secretary for consideration and potential change in existing CDC guidelines.

#### 8. Criteria for Listing Patients

The 1998 rule set as a performance goal that the OPTN standardize objective and measurable medical criteria for including patients on the waiting list. In drafting the language of

that section, the Department expected that the criteria developed for adding patients to the waiting list would inherently contain criteria for removing patients from the list. Commenters pointed out that the rule should be specific in this respect. The Department adopted this suggested clarification in § 121.8(b)(1).

#### 9. Organ Allocation

The Department received many comments on this section, especially former § 121.8(a). We have reorganized this entire section for clarity and addressed points raised by the IOM as well as several issues raised by commenters. Some commenters asked that we clarify the OPTN's ability to have different allocation policies for different types of organs (or combinations of organs) to be transplanted. Language to this effect is now found in § 121.8(a)(4). The Department wishes to emphasize that this means that the OPTN may take a different approach in defining priority ranking under § 121.8(b)(2) for organs like kidneys where the technology of renal dialysis permits some flexibility in determining the timing of a transplant. Similarly, a different approach may also be taken where such "rescue" techniques are available for other organs. Such alternatives may be used, consistent with sound medical judgment.

Other commenters suggested that the concepts of using sound medical judgment, avoidance of futile transplants or wastage of organs, and promotion of the efficient use of organs should be applicable to all the performance goals. Language adopting this suggestion is now found in § 121.8(a)(5).

We have added to § 121.8(a)(5) a provision that allocation policy seek to promote patient access to transplants, an issue Congress asked the IOM to address. As discussed above, we have also added at § 121.8(a)(7) language to promote compliance with and enforcement of approved allocation policies.

We have revised the discussion of medical urgency now found in § 121.8(b)(2). We have made clear that the need to rank patients or categories of patients in order of decreasing medical urgency only applies to otherwise medically appropriate candidates for transplants. This is consistent with the provisions found in § 121.8(a) that require allocation policies be developed in accordance with sound medical judgment and avoidance of futile transplants and organ wastage.



Some commenters suggested that the rule was unclear as to how "medical urgency" applies to kidney allocation policy. We revised this section in response to comments that the term "status categories," as currently used for liver and heart patients, is not used for kidney patients. (Instead, a point system is used to rank patients when an organ becomes available.) The use of the term "patients or categories of patients" in this section makes clear that ranking patients rather than categories of patients is permitted under this rule. As discussed above, we intend for ranking to be applied in the context of the factors listed in § 121.8(a), especially in accordance with sound medical judgment. Therefore, we believe that there may well be different approaches to kidney allocation policy than those for other types of organs, perhaps along the lines of the current policies, which take into account such factors as immunologic compatibility between the donor and patient, whether the patient's immune system is highly sensitized, and other medical factors.

Commenters suggested that the Department closely monitor the changes to allocation policies made after the initial reviews required under this section to ensure that the new policies are achieving the desired improvements in the allocation system. The Department intends to monitor the effects of these changes closely and in consultation with the OPTN. In addition to this monitoring and consultation, the Department will formally determine whether further changes are necessary six months and 12 months after the changes to allocation policies made after the initial reviews go into effect.

Finally, as discussed above, we have given the OPTN additional flexibility with respect to performance indicators, including waiting times, in response both to comments received and the IOM report.

The Department wishes to emphasize, however, that these changes are not intended to limit the ability of the OPTN to address special situations such as the unique needs of young children.

#### *10. Department of Veterans Affairs Hospitals*

The term "Dean's Committee" has been deleted from § 121.9(a)(3), as this is not a term currently used by the Department of Veterans Affairs. Currently, the Department of Veterans Affairs, Veterans Health Administration, designates specific VA medical centers to carry out organ transplantation. To cover the possibility that transplants may also be carried out in other Federal hospitals, as well as those owned and

operated by the Department of Defense (DoD), transplant programs in DoD or other Federal hospitals have been added to those eligible to receive organs for transplantation under § 121.9(a).

#### *11. Enforcement*

Section 121.10(c)(1) has been edited to clarify that appropriate enforcement action may include termination of a transplant program's reimbursement under Medicare and Medicaid. In addition, the Department wishes to clarify that the regulation permits the OPTN to develop policies that will contain lesser or intermediate level sanctions that may be taken by the OPTN, but these policies must first be approved by the Secretary in order for them to be enforceable.

#### *12. Reporting Requirements*

Section 121.11(b)(2) has been amended to include transplant program costs among the items to be reported by transplant hospitals to the OPTN and the Secretary. Although the language in the previously published final rule was sufficiently broad to permit the Secretary to specify that cost information be submitted, it was felt that its specific inclusion in the rule would ensure that such information would be made available on a timely basis when requested, consistent with section 213. Because of the difficulty in defining costs for these purposes, the Department will accept measures of resource utilization.

#### *13. Effect of the Regulation on State Laws (former § 121.12)*

The inclusion of § 121.12 in the 1998 regulation was intended to be consonant with longstanding Constitutional principles regarding the relationship between the Federal and State governments. It reflected the HHS belief that Congress intended the statutory scheme it established under NOTA to result "in the nationwide distribution of organs equitably among transplant patients." Section 372(b)(2)(D) of the Public Health Service Act. Nevertheless, because the Department views this result as flowing from the statutory scheme, the section of the regulation articulating the Department's views on the matter is unnecessary as a legal matter. Accordingly, § 121.12 has been removed.

#### *14. Advisory Committee on Organ Transplantation*

The Department intends to implement the recommendation of the IOM, as discussed above, to create an independent, multidisciplinary scientific advisory board which will

assist the Secretary in, "ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." Constitution of such an advisory committee and its consultation by the Secretary, as appropriate, in the words of the IOM, "would also enhance public confidence in the integrity and effectiveness of the system." The Department has added a new § 121.12 to provide for the establishment of an Advisory Committee on Organ Transplantation. The Committee, to be established in accordance with the Federal Advisory Committee Act [5 U.S.C. App.], will be available to the Secretary to provide comments on proposed OPTN policies and other matters related to transplantation. The Committee will be composed of individuals drawn from diverse backgrounds such as health care public policy, transplantation medicine and surgery, non-physician transplant professions, biostatistics, immunology, health economics, epidemiology, bioethics, and law. As part of this process of establishing the Committee, the Secretary intends to solicit nominations for Committee members from the transplant community and the general public.

#### **IV. Impact Analyses**

We have examined the impact of this amendatory language as required by Executive Order 12866, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). Executive Order 12866 directs agencies to assess costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize benefits. The Unfunded Mandates Reform Act of 1995 also requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may mandate an annual expenditure by State, local, or tribal governments of \$100 million or more.

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), if an action has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the effects on small business entities and analyze regulatory options that could lessen the impact of the rule.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any regulation that may have a significant impact on the operations of a substantial number of small rural hospitals.

The amendatory language set forth in this document makes no changes that have a significant economic effect on State, local or tribal governments, hospitals or patients; therefore, we certify that no additional regulatory analysis is required. We have also concluded, based on the findings of the Institute of Medicine and the General Accounting Office under section 213(b), discussed earlier in this Preamble, and the Secretary certifies, that this amendatory language would not have a significant economic impact on a substantial number of small entities; therefore, a regulatory flexibility analysis is not required.

We are also not preparing a rural impact statement since we have determined, and the Secretary certifies, that this amendatory language would not have a significant impact on the operations of a substantial number of small rural hospitals.

The earlier analyses from the April 2, 1998, final rule remain applicable to that rule and are not altered by these amendments.

#### List of Subjects in 42 CFR Part 121

Health care, Hospitals, Organ transplantation, Reporting and recordkeeping requirements.

Dated: October 13, 1999.

**Claude Earl Fox,**

*Administrator, Health Resources and Services Administration.*

Approved: October 15, 1999.

**Donna E. Shalala,**

*Secretary.*

Accordingly, 42 CFR part 121 is amended as follows:

#### PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

1. The authority citation for part 121 is revised to read as follows:

**Authority:** Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh).

2. Paragraph (b) of § 121.1 is revised to read as follows:

##### § 121.1 Applicability.

\* \* \* \* \*

(b) In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

3. Amend § 121.2 as follows:

a. Remove the definition for the “National list”.

b. Amend the definition of “OPTN computer match program” by revising the words “national list” to read “waiting list”.

c. Amend the definition of “Organ” by removing the words “and for the purpose of the Scientific Registry, the term also includes bone marrow”.

d. Amend the definition of “Organ procurement organization” by revising the words “Section 1138(b)” to read “section 1138(b)”.

e. Amend the definition of “Organ procurement and transplantation network or OPTN” by revising the words “Section 372” to read “section 372”.

f. Amend the definition of “Scientific Registry” by revising the words “Section 373” to read “section 373”.

g. Amend the definition of “Transplant candidate” by revising the words national list” to read “waiting list”.

h. Add a definition for “Waiting list” in alphabetical order.

The addition reads as follows:

##### § 121.2 Definitions.

\* \* \* \* \*

*Waiting list* means the OPTN computer-based list of transplant candidates.

4. Amend § 121.3 as follows:

a. Revise the heading of paragraph (a).

b. Revise paragraph (a)(1).

c. Remove paragraph (a)(2).

d. Remove paragraph (a)(3).

e. Remove paragraph (a)(4).

f. Remove the heading of paragraph (b).

g. Redesignate paragraph (b)(1) as paragraph (a)(2) and revise it.

h. Redesignate paragraph (b)(2) as paragraph (a)(3) and amend the newly designated paragraph (a)(3) by removing the paragraph heading.

i. Redesignate paragraph (b)(3) as paragraph (a)(4) and amend newly designated paragraph (a)(4) by removing the paragraph heading.

j. In newly designated paragraph (a)(4)(ii), revise the term “potential transplant candidates” to read “transplant candidates, transplant recipients, organ donors and family members”.

k. Remove paragraph (b)(4).

l. Redesignate paragraph (c) as paragraph (b).

m. Redesignate paragraph (d) as paragraph (c) and revise the word “Status” in the heading to read “status”.

n. Redesignate paragraph (e) as paragraph (d) and revise it.

The revisions read as follows:

##### § 121.3 The OPTN.

(a) *Organization of the OPTN.* (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate. The Board of Directors shall include:

(i) Approximately 50 percent transplant surgeons or transplant physicians;

(ii) At least 25 percent transplant candidates, transplant recipients, organ donors and family members. These members should represent the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN including, to the extent practicable, the minority and gender diversity of this population. These members shall not be employees of, or have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals; however, the Board may waive this requirement for not more than 50 percent of these members; and

(iii) Representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.

(2) The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one general public member, one OPO representative, approximately 50 percent transplant surgeons and transplant physicians, and at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

\* \* \* \* \*

(d) *Effective date.* The organization designated by the Secretary as the OPTN shall have until June 30, 2000, or six months from its initial designation as the OPTN, whichever is later, to meet the requirements of this section, except that the Secretary may extend such period for good cause.

5. Amend § 121.4 as follows:

a. Revise paragraph (a)(3)(i).

b. Revise paragraph (a)(3)(ii).

c. Revise paragraph (b)(2).

d. Revise paragraph (c).

e. Revise paragraph (d).

f. Amend paragraph (e) introductory text by adding the word “shall” after the words “implement policies and”, and by revising the word “them.” in paragraph (e)(1) to read “them; and”.

The revisions read as follows:

**§ 121.4. OPTN policies: Secretarial review and appeals.**

(a) \* \* \*

(3) \* \* \*

(i) Ensuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee;

(ii) Procedures for transplant hospitals to make reasonable efforts to obtain from all available sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

\* \* \* \* \*

(b) \* \* \*

(2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the **Federal Register** for public comment. The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under § 121.12 on other proposed policies, and publish them in the **Federal Register** for public comment. The Secretary will determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments. Based on this review, the Secretary may provide comments to the OPTN. If the Secretary concludes that a proposed policy is inconsistent with the National Organ Transplant Act or this part, the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the National Organ Transplant Act or this part, the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee on the proposed action.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of its policies as they are adopted, and make them available to the public upon request.

The Secretary will publish lists of OPTN policies in the **Federal Register**, indicating which ones are enforceable under § 121.10 or subject to potential sanctions of section 1138 of the Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under § 121.12. After this review, the Secretary may:

(1) Reject the comments;

(2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or

(3) Take such other action as the Secretary determines appropriate.

\* \* \* \* \*

**§ 121.5 [Amended]**

6. Amend § 121.5 as follows:

a. In paragraph (a), add the words "consistent with the OPTN's criteria under § 121.8(b)(1)," after the word "individuals".

b. In paragraph (b), revise the words "national list" to read "waiting list".

c. In paragraph (c), revise the words "national list" to read "waiting list" and add the phrase "calculated to cover (together with contract funds awarded by the Secretary) the reasonable costs of operating the OPTN and shall be" after the words "amount of such fee shall be".

7. Paragraph (b) of § 121.6 is revised to read as follows:

**§ 121.6 Organ procurement.**

\* \* \* \* \*

(b) *HIV*. The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.

\* \* \* \* \*

**§ 121.7 [Amended]**

8. Paragraph (d) of § 121.7 is amended by revising the words "paragraph (b) of this section" to read "paragraph (b)(2) of this section".

9. Revise § 121.8 to read as follows:

**§ 121.8 Allocation of organs.**

(a) *Policy development*. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

(b) *Allocation performance goals*. Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

(1) Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists;

(2) Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings

shall be ordered from most to least medically urgent (taking into account, in accordance with paragraph (a) of this section, and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency;

(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)–(5) of this section, and in order of decreasing medical urgency; and

(4) Applying appropriate performance indicators to assess transplant program performance under paragraphs (c)(2)(i) and (c)(2)(ii) of this section and reducing the inter-transplant program variance to as small as can reasonably be achieved in any performance indicator under paragraph (c)(2)(iii) of this section as the Board determines appropriate, and under paragraph (c)(2)(iv) of this section. If the performance indicator “waiting time in status” is used for allocation purposes, the OPTN shall seek to reduce the inter-transplant program variance in this indicator, as well as in other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

(c) *Allocation performance indicators.* (1) Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is:

(i) Achieving the performance goals set out in paragraph (b) of this section; and

(ii) Giving patients, their families, their physicians, and others timely and accurate information to assess the performance of transplant programs.

(2) Performance indicators shall include:

(i) Baseline data on how closely the results of current allocation policies approach the performance goals established under paragraph (b) of this section;

(ii) With respect to any proposed change, the amount of projected improvement in approaching the performance goals established under paragraph (b) of this section;

(iii) Such other indicators as the Board may propose and the Secretary approves; and

(iv) Such other indicators as the Secretary may require.

(3) For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor. Such data shall be required on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the Nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include the following measures of inter-transplant program variation: risk-adjusted total life-years pre- and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as may be required to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(d) *Transition patient protections.*—

(1) *General.* When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(2) *Special rule for initial revision of liver allocation policies.* When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (e)(1) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the waiting list and awaiting transplantation on October 20, 1999 no less favorably than he or she would have been treated had the revised liver allocation policies not become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those

disadvantaged by the change in the policies.

(e) *Deadlines for initial reviews.* (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (e)(2) of this section, no later than November 16, 2000 shall transmit initial revised policies to meet the requirements of paragraphs (a) and (b) of this section, together with supporting documentation to the Secretary for review in accordance with § 121.4.

(2) No later than February 15, 2000 the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of paragraphs (a) and (b) of this section to the Secretary for review in accordance with § 121.4. The OPTN may transmit these materials without seeking further public comment under § 121.4(b).

(f) *Secretarial review of policies, performance indicators, and transition patient protections.* The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraphs (c) and (d) of this section.

(g) *Variances.* The OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of § 121.4.

(h) *Directed donation.* Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

10. Amend § 121.9 as follows:

a. Amend paragraph (a)(1) by removing the words “and Medicaid” after the word “Medicare”.

b. Amend paragraph (a)(2)(vi) by adding a comma after the word “radiology”.

c. Amend paragraph (a)(2)(vii) by adding a comma after the word “recipients”.

d. Revise paragraph (a)(3).

The revision reads as follows:

#### § 121.9 Designated transplant program requirements.

(a) \* \* \*

(3) Be a transplant program in a Department of Veterans Affairs,

Department of Defense, or other Federal hospital.

\* \* \* \* \*

**§ 121.10 [Amended]**

11. Amend paragraph (c)(1) of § 121.10 by removing the word “or” before the words “termination of an OPO’s reimbursement”, and by adding the words “, or such other compliance or enforcement measures contained in policies developed under § 121.4” after the words “Social Security Act”.

12. Amend § 121.11 as follows:

a. Revise paragraph (a)(1)(i) by removing the word “national” after the word “computerized”.

b. Revise paragraph (b)(1)(iv).

c. Amend paragraph (b)(2) by adding the words “costs and” before the word “performance”.

The revision reads as follows:

**§ 121.11 Record maintenance and reporting requirements.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months (or such longer period as the Secretary determines would provide more useful information to patients, their families, and their physicians), and shall include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe. These data shall include confidence intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results.

Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

\* \* \* \* \*

13. § 121.12 is revised to read as follows:

**§ 121.12 Advisory Committee on Organ Transplantation.**

The Secretary will establish, consistent with the Federal Advisory Committee Act, the Advisory Committee on Organ Transplantation. The Secretary may seek the comments of the Advisory Committee on proposed OPTN policies and such other matters as the Secretary determines.

[FR Doc. 99-27456 Filed 10-18-99; 9:46 am]

BILLING CODE 4160-15-P



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Wednesday  
October 20, 1999

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## Part VII

# The President

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Proclamation 7242—National Character  
Counts Week, 1999

Notice of October 19, 1999—Continuation  
of Emergency With Respect to Significant  
Narcotics Traffickers Centered in  
Colombia





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# Presidential Documents

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Title 3—

Proclamation 7242 of October 16, 1999

The President

National Character Counts Week, 1999

By the President of the United States of America

## A Proclamation

The character of our citizens has enriched every aspect of our national life and has set an example of civic responsibility for people around the world. The diligence and determination that are part of our Nation's work ethic have strengthened our economy, and the firm convictions of our spiritual leaders have helped guide our communities, fostering unity, compassion, and humility.

In this dynamic time of unparalleled opportunity and possibility, our children will encounter a variety of new challenges that will test the strength of their character and convictions. As the dawn of the new millennium fast approaches, we must work together—parents, public officials, educators, entertainers, and business and religious leaders—to impart to our youth the core values they need to be good citizens.

We know that parents play a critical role in imparting moral values to their children. But in today's complex and fast-paced society, when parents must spend longer hours at work and more families are headed by a single parent, parents have less time to spend with their children—an average decrease of 22 hours a week over the past 30 years, according to a report released this spring by my Council of Economic Advisers. We must seek innovative ways to address this problem and to promote stronger families, including greater flexibility in paid work hours, more affordable child care, and increased support for low-income families.

My Administration is committed to providing families with the tools they need to fulfill their responsibilities at home and at work. Our agenda includes tripling our investment in after-school programs through the 21st Century Community Learning Center program and a historic initiative to make child care better, safer, and more affordable for working families. We are also working to expand the Family and Medical Leave Act to cover more workers and to allow leave for more parental activities, such as parent-teacher conferences and routine doctor visits.

While Americans are striving to seize the opportunities presented by this exciting new era, we must continue to preserve the fundamental ideals and ethics that have sustained our country for more than two centuries. By sustaining these shared values and passing them on to our children, we can realize our common hope for a more just and honorable society and a brighter future for the generations to come.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 17 through October 23, 1999, as National Character Counts Week. I call upon the people of the United States, government officials, educators, religious, community, and business leaders, and the States to commemorate this week with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of October, in the year of our Lord nineteen hundred and ninety-nine, and of the Independence of the United States of America the two hundred and twenty-fourth.

*William Clinton*

[FR Doc. 99-27644

Filed 10-19-99; 11:37 am]

Billing code 3195-01-P

## Presidential Documents

Notice of October 19, 1999

### Continuation of Emergency With Respect to Significant Narcotics Traffickers Centered in Colombia

On October 21, 1995, by Executive Order 12978, I declared a national emergency to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions of significant foreign narcotics traffickers centered in Colombia, and the unparalleled violence, corruption, and harm that they cause in the United States and abroad. The order blocks all property and interests in property of foreign persons listed in an Annex to the order, as well as foreign persons determined to play a significant role in international narcotics trafficking centered in Colombia, to materially assist in, or provide financial or technological support for or goods or services in support of, the narcotics trafficking activities of persons designated in or pursuant to the order, or to be owned or controlled by, or to act for or on behalf of, persons designated in or pursuant to the order. The order also prohibits any transaction or dealing by United States persons or within the United States in such property or interests in property. Because the activities of significant narcotics traffickers centered in Colombia continue to threaten the national security, foreign policy, and economy of the United States and to cause unparalleled violence, corruption, and harm in the United States and abroad, the national emergency declared on October 21, 1995, and the measures adopted pursuant thereto to respond to that emergency, must continue in effect beyond October 21, 1999. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency for 1 year with respect to significant narcotics traffickers centered in Colombia.

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



THE WHITE HOUSE,  
October 19, 1999.

# Reader Aids

## Federal Register

Vol. 64, No. 202

Wednesday, October 20, 1999

### CUSTOMER SERVICE AND INFORMATION

#### Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-523-5227**

**Laws** **523-5227**

#### Presidential Documents

Executive orders and proclamations **523-5227**

**The United States Government Manual** **523-5227**

#### Other Services

Electronic and on-line services (voice) **523-4534**

Privacy Act Compilation **523-3187**

Public Laws Update Service (numbers, dates, etc.) **523-6641**

TTY for the deaf-and-hard-of-hearing **523-5229**

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### FEDERAL REGISTER PAGES AND DATE, OCTOBER

53179-53580.....	1
53581-53882.....	4
53883-54198.....	5
54199-54498.....	6
54499-54758.....	7
54759-55114.....	8
55115-55404.....	12
55405-55614.....	13
55615-55808.....	14
55809-56130.....	15
56131-56250.....	18
56251-56398.....	19
56399-56668.....	20

### 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

##### Proclamations:

4865 (See  
Memorandum of  
April 16, 1999) .....53883

4865 (See  
Memorandum of  
September 24,  
1999) .....53883

6763 (See  
Proclamation  
7235) .....55611

7227 .....53877

7228 .....54193

7229 .....54195

7230 .....54197

7231 .....54755

7232 .....54757

7233 .....54759

7234 .....55405

7235 .....55611

7236 .....55613

7237 .....55615

7238 .....55617

7239 .....55619

7240 .....56393

7241 .....56397

7242 .....56665

##### Executive Orders:

11145 (Amended by  
EO 13138) .....53879

11183 (Amended by  
EO 13138) .....53879

11287 (Amended by  
EO 13138) .....53879

12131 (Amended by  
EO 13138) .....53879

12196 (Amended by  
EO 13138) .....53879

12216 (Amended by  
EO 13138) .....53879

12345 (Amended by  
EO 13138) .....53879

12367 (Amended by  
EO 13138) .....53879

12382 (Amended by  
EO 13138) .....53879

12473 (Amended by  
EO 13140) .....55115

12478 (See EO  
13140) .....55115

12550 (See EO  
13140) .....55115

12586 (See EO  
13140) .....55115

12708 (See EO  
13140) .....55115

12767 (See EO  
13140) .....55115

12852 (Revoked by  
EO 13138) .....53879

12871 (Amended by

EO 13138) .....53879

12876 (Amended by  
EO 13138) .....53879

12882 (Amended by  
EO 13138) .....53879

12888 (See EO  
13140) .....55115

12900 (Amended by  
EO 13138) .....53879

12905 (Amended by  
EO 13138) .....53879

12936 (See EO  
13140) .....55115

12960 (See EO  
13140) .....55115

12961 (Revoked by  
EO 13138) .....53879

12978 (See Notice of  
October 19, 1999) .....56667

12994 (Amended by  
EO 13138) .....53879

13010 (Revoked in  
part by EO  
13138) .....53879

13017 (Revoked by  
EO 13138) .....53879

13021 (Amended by  
EO 13138) .....53879

13037 (Revoked by  
EO 13138) .....53879

13038 (Revoked by  
EO 13138) .....53879

13050 (Revoked by  
EO 13138) .....53879

13062 (Superseded in  
part by EO  
13138) .....53879

13086 (See EO  
13140) .....55115

13115 (Amended by  
EO 13138) .....53879

13138 .....53879

13139 .....54175

13140 .....55115

##### Administrative Orders:

Memorandums:

April 16, 1999 .....53883

September 24, 1999 .....55809

Notice of October 19,  
1999 .....56667

Presidential Determinations:

No. 99-38 of  
September 21,  
1999 .....53573

No. 99-39 of  
September 21,  
1999 .....53575

No. 99-40 of  
September 21,  
1999 .....53577

No. 99-41 of  
September 22,  
1999 .....53579

No. 99-42 of September 29, 1999 .....	54499
No. 99-43 of September 30, 1999 .....	54501
No. 99-44 of September 30, 1999 .....	54503
No. 99-45 of September 30, 1999 .....	53505

**5 CFR**

532 .....	53179
831 .....	53581
842 .....	53581
870 .....	54761
1201 .....	54507

**7 CFR**

210 .....	55407
215 .....	55407
220 .....	55407
235 .....	55407
245 .....	55407
301 .....	55811
735 .....	54508
915 .....	53181
923 .....	53885
944 .....	53181
984 .....	56131
997 .....	56133
998 .....	56133
999 .....	56133
1000 .....	53885
1001 .....	53885
1002 .....	53885
1004 .....	53885
1005 .....	53885
1006 .....	53885
1007 .....	53885
1012 .....	53885
1013 .....	53885
1030 .....	53885
1032 .....	53885
1033 .....	53885
1036 .....	53885
1040 .....	53885
1044 .....	53885
1046 .....	53885
1049 .....	53885
1050 .....	53885
1064 .....	53885
1065 .....	53885
1068 .....	53885
1076 .....	53885
1079 .....	53885
1106 .....	53885
1124 .....	53885
1126 .....	53885
1131 .....	53885
1134 .....	53885
1135 .....	53885
1137 .....	53885
1138 .....	53885
1139 .....	53885
1755 .....	53886
2003 .....	56399
3570 .....	56399

**8 CFR**

3 .....	56135
<b>Proposed Rules:</b>	
Ch. 1 .....	54794

**9 CFR**

3 .....	56142
77 .....	56399
94 .....	55812, 55813
303 .....	56400
304 .....	56400
307 .....	56400
308 .....	56400
312 .....	56400
314 .....	56400
317 .....	53186
327 .....	56400
331 .....	56400
350 .....	56400
381 .....	53186, 56400
416 .....	56400

**10 CFR**

20 .....	54543, 55524
50 .....	53582
72 .....	53582, 56114
431 .....	54114
600 .....	56418

**Proposed Rules:**

2 .....	55176
20 .....	56274
50 .....	53270, 56476

**11 CFR**

110 .....	55125
<b>Proposed Rules:</b>	
100 .....	55440
102 .....	55440
104 .....	55440

**12 CFR**

204 .....	53617
262 .....	53188
602 .....	54511
612 .....	55621
614 .....	55621
618 .....	55621
741 .....	56148
910 .....	55125
<b>Proposed Rules:</b>	
714 .....	55866
724 .....	55871
745 .....	55871
1750 .....	56274

**13 CFR**

<b>Proposed Rules:</b>	
121 .....	55873

**14 CFR**

25 .....	54761
36 .....	55598
39 .....	53189, 53191, 53193, 53620, 53621, 53623, 53625, 54199, 54200, 54202, 54512, 54513, 54515, 54517, 54518, 54763, 54767, 54769, 54770, 54773, 54774, 55407, 55409, 55411, 55413, 55414, 55416, 55621, 55624, 55815, 56151, 56158, 56158, 56159, 56161, 56163, 56420, 56422, 56424, 56426

71 .....	53627, 53887, 53888, 53889, 53890, 53891, 53892, 53893, 53894, 53895, 53896, 53898, 53899, 54203, 54204, 54205, 54206, 55131, 55815, 55816, 55817, 55818, 55819, 55820, 56251, 56428, 56429
----------	---

93 .....	53558
97 .....	55132, 55133, 55135
<b>Proposed Rules:</b>	
Ch. 1 .....	56275
39 .....	53275, 53951, 53953, 54227, 54229, 54230, 54232, 54234, 54237, 54239, 54240, 54242, 54246, 54248, 54249, 54580, 54582, 54584, 54587, 54589, 54591, 54594, 54596, 54598, 54795, 54797, 54799, 54801, 54804, 54808, 54811, 54815, 54818, 54822, 54826, 54829, 54833, 55177, 55181, 55184, 55188, 55191, 55195, 55196, 55197, 55200, 55204, 55207, 55211, 55440, 55636, 55638, 55640, 55642, 55644, 56276, 56279, 56281
71 .....	53956, 53957
193 .....	53958
450 .....	54448

**15 CFR**

774 .....	54520
902 .....	54732, 55821
2014 .....	56429

**Proposed Rules:**

30 .....	53861
732 .....	53854
740 .....	53854
743 .....	53854
748 .....	53854
750 .....	53854
752 .....	53854
758 .....	53854
762 .....	53854
772 .....	53854

**17 CFR**

210 .....	53900
228 .....	53900
229 .....	53900
230 .....	53900
232 .....	56430
239 .....	53900, 56430
240 .....	53900
249 .....	53900, 56430
259 .....	56430
260 .....	53900
269 .....	56430
274 .....	56430

**Proposed Rules:**

210 .....	55648
228 .....	55648
229 .....	55648
240 .....	55648

**18 CFR**

2 .....	54522
157 .....	54522
284 .....	54522
380 .....	54522
385 .....	54522, 56172
<b>Proposed Rules:</b>	
385 .....	53959

**19 CFR**

24 .....	56433
122 .....	53627
159 .....	56433
174 .....	56433

**20 CFR**

<b>Proposed Rules:</b>	
404 .....	55214

422 .....	55216
718 .....	54966
722 .....	54966
725 .....	54966
726 .....	54966
727 .....	54966

**21 CFR**

Ch. II .....	54794
3 .....	56441
5 .....	56441
10 .....	56441
20 .....	56441
25 .....	56454
50 .....	54180, 56441
56 .....	56441
58 .....	56441
173 .....	56172
178 .....	53925
207 .....	56441
310 .....	56441
312 .....	54180, 56441
316 .....	56441
558 .....	53926
600 .....	56441
601 .....	56441
607 .....	56441
610 .....	56441
640 .....	56441
660 .....	56441
878 .....	53927
900 .....	53195

**Proposed Rules:**

5 .....	53281
25 .....	53281
314 .....	53960
500 .....	53281
510 .....	53281
558 .....	53281
601 .....	53960
880 .....	53294

**22 CFR**

Ch. V .....	54538
40 .....	55417
42 .....	55417
171 .....	54538
514 .....	53928

**Proposed Rules:**

194 .....	53632
-----------	-------

**24 CFR**

200 .....	53930, 55828
203 .....	56108
234 .....	56108
882 .....	53868
888 .....	53450

**25 CFR**

516 .....	54541
<b>Proposed Rules:</b>	
151 .....	55878

**26 CFR**

1 .....	55137
301 .....	56246
<b>Proposed Rules:</b>	
1 .....	54836, 56246
25 .....	56179

**27 CFR**

1 .....	54776
47 .....	55625
55 .....	55625

**28 CFR**

Ch. I .....	54794
-------------	-------

<b>Proposed Rules:</b>	55139, 55141, 55421, 55831	<b>Proposed Rules:</b>	97.....53231
571.....53872	61.....53212	302.....55074	101.....53231
<b>29 CFR</b>	62.....55141	303.....55074	<b>Proposed Rules:</b>
4044.....55828	63.....56173	304.....55074	54.....53648
<b>30 CFR</b>	76.....55834	305.....55074	61.....53648
202.....56454	81.....55421	308.....55102	69.....53648
206.....56454	180.....54218, 54777, 54779,	<b>46 CFR</b>	73.....53655, 54268, 54269,
250.....53195	55838, 56464	1.....53220	54270, 55222, 55223, 55452,
948.....53200	201.....55141	2.....53220	55453
950.....53202	261.....56256, 56469	4.....53220	76.....54854
<b>Proposed Rules:</b>	262.....56469	10.....53220, 53230	<b>48 CFR</b>
250.....53298	268.....56469	12.....53230	Ch. 19.....54538
901.....55878	271.....55142, 55153, 55629,	15.....53220	1.....53264
904.....56179	56173	27.....56257	15.....53264
915.....54840	300.....53213, 53629	31.....53220	19.....53264
946.....54843	<b>Proposed Rules:</b>	34.....53220	52.....53264
948.....54845	49.....54851	38.....53220	209.....55632
<b>32 CFR</b>	52.....53303, 53973, 54600,	52.....53220	211.....55632
700.....56062	54601, 54851, 55219, 55220,	53.....53220	214.....55632
1800.....53769	55442, 55662, 55667, 55879,	54.....53220	237.....53447
<b>Proposed Rules:</b>	56181	56.....53220	252.....55632
199.....56283	76.....55880	57.....53220	415.....54963
806.....56181	81.....55442	58.....53220	<b>Proposed Rules:</b>
<b>33 CFR</b>	122.....53304	59.....53220	909.....55453
100.....53208, 53628, 55829,	123.....53304	61.....53220	970.....55453
55830	124.....53304	63.....53220	1804.....54270
117.....53209, 54776, 55137,	130.....53304	64.....53220	1812.....54270
55419, 55831, 56252	131.....53304	67.....53220	1852.....54270
165.....55138, 55420	132.....53632	68.....53220	9903.....56296
<b>Proposed Rules:</b>	180.....56477	69.....53220	<b>49 CFR</b>
Ch. I.....56286	194.....56185	76.....53220	1.....56270
20.....53970	197.....53304	91.....53220	172.....54730
100.....54847, 54849	258.....53976	95.....53220	Ch. III.....56478
117.....55217	261.....55443, 55880	98.....53220	1002.....53264
165.....54242, 54963	264.....54604	105.....53220	1003.....53264
175.....53971	271.....55222, 55671	107.....53220	1007.....53264
181.....56287	<b>41 CFR</b>	108.....53220	1011.....53264
183.....56287	51-2.....55841	109.....53220	1012.....53264
207.....55441	51-5.....55841	118.....53220	1014.....53264
<b>34 CFR</b>	<b>42 CFR</b>	125.....53220	1017.....53264
602.....56612	121.....56650	133.....53220	1018.....53264
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	147.....53220	1019.....53264
75.....54254	8.....56294	151.....53220	1021.....53264
<b>36 CFR</b>	57.....54263	153.....53220	1024.....53264
13.....56455	58.....54263	160.....53220	1034.....53264
<b>Proposed Rules:</b>	447.....54263	161.....53220	1039.....53264
217.....59074, 56293	<b>43 CFR</b>	162.....53220	1100.....53264
219.....59074, 56293	1820.....53213	167.....53220	1101.....53264
<b>37 CFR</b>	3500.....53512	169.....53220	1103.....53264
<b>Proposed Rules:</b>	3510.....53512	177.....53220	1104.....53264
1.....53772	3520.....53512	181.....53220	1105.....53264
3.....53772	3530.....53512	189.....53220	1113.....53264
5.....53772	3540.....53512	193.....53220	1133.....53264
10.....53772	3550.....53512	197.....53220	1139.....53264
<b>38 CFR</b>	3560.....53512	199.....53220	1150.....53264
3.....54206	3570.....53512	204.....54782	1151.....53264
17.....54207	3800.....53213	<b>Proposed Rules:</b>	1152.....53264
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	5.....53970	1177.....53264
20.....53302	2800.....55452	<b>47 CFR</b>	1180.....53264
<b>39 CFR</b>	2880.....55452	Ch. I.....54561, 55671	1184.....53264
776.....56253	<b>44 CFR</b>	0.....55161, 55425, 56269	<b>Proposed Rules:</b>
<b>Proposed Rules:</b>	62.....56174	1.....53231	71.....55892
111.....54255	64.....56256	13.....53231	661.....54855
<b>40 CFR</b>	65.....53931, 53933, 53936	20.....54564	<b>50 CFR</b>
52.....53210, 53931, 54559,	67.....53938, 53939	22.....53231, 54564	17.....56582, 56590, 56596
	206.....55158	64.....53242, 53944, 54577,	216.....53269
	<b>Proposed Rules:</b>	55163, 55164, 56177	222.....55858, 55860
	67.....53980, 53982	73.....54224, 54225, 54783,	223.....55434, 55858, 55860
	<b>45 CFR</b>	54784, 54785, 54786, 55172,	600.....54786
	96.....55843	55173, 55174, 55434	635.....53949, 54577, 55633,
		80.....53231	56472
		87.....53231	648.....54732, 55821
		90.....53231	660.....54786, 56177
		95.....53231	679.....53630, 53950, 54225,

54578, 54791, 54792, 55438,	227 .....	56297
55634, 55865, 56271, 56272,	648 .....	55688
56473, 56474, 56475	660 .....	54272, 55689, 56479
<b>Proposed Rules:</b>	679 .....	53305, 56481
17 .....		53655, 55892, 56297
216 .....		56298

**REMINDERS**

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

**RULES GOING INTO EFFECT OCTOBER 20, 1999****AGRICULTURE DEPARTMENT****Agricultural Marketing Service**

Cherries (tart) grown in—  
Michigan et al.; published 9-20-99

**AGRICULTURE DEPARTMENT****Food and Nutrition Service**

Child nutrition programs:

- National school lunch program—  
Technical amendments; published 9-20-99
- Technical amendments; correction; published 10-13-99

**AGRICULTURE DEPARTMENT****Farm Service Agency**

Program regulations:  
Community facilities grant program  
Correction; published 10-20-99

**AGRICULTURE DEPARTMENT****Rural Business-Cooperative Service**

Program regulations:  
Community facilities grant program  
Correction; published 10-20-99

**AGRICULTURE DEPARTMENT****Rural Utilities Service**

Program regulations:  
Community facilities grant program  
Correction; published 10-20-99  
Correction; published 10-20-99

**ENVIRONMENTAL PROTECTION AGENCY**

Hazardous waste:

- Land disposal restrictions—  
Wood preserving wastes, metal wastes, zinc micronutrient fertilizers, etc.; correction; published 10-20-99
- Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Pyrithiobac sodium salt; published 10-20-99

**INTERIOR DEPARTMENT****National Park Service**

National Park System:

- Glacier Bay National Park, AK; commercial fishing activities; published 10-20-99

**NUCLEAR REGULATORY COMMISSION**

Operators' licenses:

- Initial examination requirements; published 4-23-99

**TRANSPORTATION DEPARTMENT****Federal Aviation Administration**

Airworthiness directives:

- Airbus; published 9-15-99
- Boeing; published 9-15-99
- Dassault; published 9-15-99
- Empresa Brasileira de Aeronautica S.A.; published 9-15-99
- Saab; published 9-15-99

**TREASURY DEPARTMENT****Customs Service**

Financial and accounting procedures:  
Customs duties, taxes, fees and interest; underpayments and overpayments interest; published 10-20-99

**COMMENTS DUE NEXT WEEK****AGRICULTURE DEPARTMENT****Agricultural Marketing Service**

Olive oil promotion, research, and information order; comments due by 10-25-99; published 8-26-99  
Referendum procedures; comments due by 10-25-99; published 8-26-99

Oranges, grapefruit, tangerines, and tangelos grown in—  
Florida; comments due by 10-27-99; published 9-27-99

**AGRICULTURE DEPARTMENT****Animal and Plant Health Inspection Service**

Hawaiian and territorial quarantine notices:  
Baggage inspection for domestic flights from Puerto Rico to U.S. Virgin Islands; comments due by 10-29-99; published 8-30-99

**COMMERCE DEPARTMENT****National Oceanic and Atmospheric Administration**

Fishery conservation and management:

- Alaska; fisheries of Exclusive Economic Zone—
- North Pacific groundfish; comments due by 10-29-99; published 10-14-99
- Pollock; comments due by 10-29-99; published 10-20-99
- Caribbean, Gulf, and South Atlantic fisheries—
- Pelagic sargassum habitat in South Atlantic; comments due by 10-25-99; published 8-26-99
- Northeastern United States fisheries—
- Northeast multispecies; comments due by 10-28-99; published 9-13-99
- West Coast States and Western Pacific fisheries—
- Pacific Coast groundfish; comments due by 10-25-99; published 10-8-99

**COMMODITY FUTURES TRADING COMMISSION**

Commodity Exchange Act:

- Electronic signatures by customers, participants, and clients of registrants; comments due by 10-29-99; published 8-30-99

Foreign futures and options transactions:

- Board of trade members; registration or exemption from registration; clarification; comments due by 10-25-99; published 8-26-99

Foreign firms acting as futures commission merchants or introducing brokers; direct acceptance of orders from U.S. customers without registering with agency; comments due by 10-25-99; published 8-26-99

**ENVIRONMENTAL PROTECTION AGENCY**

Air pollution; standards of performance for new stationary sources:

- Small municipal waste combustion units—
- Emission guidelines; comments due by 10-29-99; published 8-30-99

New source performance standards; comments due by 10-29-99; published 8-30-99

Air programs; approval and promulgation; State plans for designated facilities and pollutants:

California; comments due by 10-25-99; published 9-23-99

Air quality implementation plans; approval and promulgation; various States:

California; comments due by 10-25-99; published 9-24-99

Connecticut; comments due by 10-28-99; published 9-28-99

Maryland; comments due by 10-25-99; published 9-23-99

Massachusetts; comments due by 10-27-99; published 9-27-99

New Hampshire; comments due by 10-29-99; published 9-29-99

Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:

Colorado; comments due by 10-25-99; published 9-24-99

Hazardous waste program authorizations:

Vermont; comments due by 10-25-99; published 9-24-99

Hazardous waste:

Land disposal restrictions—  
Mercury-bearing wastes; treatment standards; comments due by 10-26-99; published 7-27-99

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Desmedipham; comments due by 10-25-99; published 8-25-99

Pyridate; comments due by 10-25-99; published 8-25-99

Superfund program:

National oil and hazardous substances contingency plan—

National priorities list update; comments due by 10-25-99; published 9-23-99

Toxic substances:

Inventory update rule; amendments; comments



due by 10-25-99;  
published 8-26-99

# **FEDERAL COMMUNICATIONS COMMISSION**

Common carrier services:

Integrated interstate  
universal service and  
interstate access reform  
plan covering price cap  
incumbent local exchange  
carriers; comments due  
by 10-29-99; published  
10-4-99

Telecommunications Act of  
1996; implementation—

Access charge reform;  
local exchange carriers  
price cap performance  
review; comments due  
by 10-29-99; published  
9-22-99

Radio services, special:

Maritime services—

Privately owned  
accounting authorities;  
accounts settlement;  
streamlining; biennial  
regulatory review;  
comments due by 10-  
25-99; published 9-3-99

Radio stations; table of  
assignments:

Oregon; comments due by  
10-25-99; published 9-16-  
99

# **FEDERAL DEPOSIT INSURANCE CORPORATION**

Assessments:

Risk classifications; capital  
component; reporting date  
change; comments due by  
10-25-99; published 9-8-  
99

# **FEDERAL RESERVE SYSTEM**

Consumer leasing (Regulation  
M):

Disclosure requirements;  
delivery by electronic  
communication; comments  
due by 10-29-99;  
published 9-14-99

Electronic fund transfers  
(Regulation E):

Disclosure requirements;  
delivery by electronic  
communication; comments  
due by 10-29-99;  
published 9-14-99

Equal credit opportunity  
(Regulation B):

Disclosure requirements;  
delivery by electronic  
communication; comments

due by 10-29-99;  
published 9-14-99

Truth in lending (Regulation  
Z):

Disclosure requirements;  
delivery by electronic  
communication; comments  
due by 10-29-99;  
published 9-14-99

Truth in savings (Regulation  
DD):

Disclosure requirements;  
delivery by electronic  
communication; comments  
due by 10-29-99;  
published 9-14-99

# **HEALTH AND HUMAN SERVICES DEPARTMENT**

## **Food and Drug Administration**

Animal drugs, feeds, and  
related products:

Sheep as minor species;  
comments due by 10-26-  
99; published 7-26-99

Medical devices

Surgeon's and patient  
examination gloves;  
reclassification; comments  
due by 10-28-99;  
published 7-30-99

## **INTERIOR DEPARTMENT**

### **Land Management Bureau**

Minerals management:

Mining claims or sites;  
location, recording, and  
maintenance; reporting  
and recordkeeping  
requirements; comments  
due by 10-26-99;  
published 8-27-99

Mining claims or sites;  
location, recording, and  
maintenance; comments  
due by 10-26-99;  
published 8-27-99

Mining claims or sites;  
location, recording, and  
maintenance; reporting  
and recordkeeping  
requirements

Correction; comments due  
by 10-26-99; published  
9-8-99

## **INTERIOR DEPARTMENT Surface Mining Reclamation and Enforcement Office**

Permanent program and  
abandoned mine land  
reclamation plan  
submissions:

Iowa; comments due by 10-  
25-99; published 10-8-99

West Virginia; comments  
due by 10-25-99;  
published 10-8-99

## **TRANSPORTATION DEPARTMENT**

### **Coast Guard**

Anchorage regulations:

Florida; comments due by  
10-29-99; published 8-30-  
99

Drawbridge operations:

Maine; comments due by  
10-25-99; published 8-25-  
99

Regattas and marine parades:

International Tug-of-War;  
comments due by 10-25-  
99; published 10-8-99

## **TRANSPORTATION DEPARTMENT**

### **Federal Aviation Administration**

Airworthiness directives:

Boeing; comments due by  
10-25-99; published 8-25-  
99

Burkhart Grob Luft-Und  
Raumfahrt GmbH & CO  
KG; comments due by  
10-29-99; published 9-29-  
99

Cessna; comments due by  
10-25-99; published 9-10-  
99

Pilatus Aircraft Ltd.;  
comments due by 10-27-  
99; published 9-28-99

Raytheon; comments due by  
10-27-99; published 8-31-  
99

Saab; comments due by 10-  
25-99; published 9-23-99

Class D and Class E

airspace; comments due by  
10-29-99; published 9-14-99

Class E airspace; comments  
due by 10-25-99; published  
9-14-99

## **TRANSPORTATION DEPARTMENT**

### **Research and Special Programs Administration**

Pipeline safety:

Hazardous liquid  
transportation—

Underwater abandoned  
pipeline facilities;  
comments due by 10-  
29-99; published 8-30-  
99

## **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 202-523-  
6641. This list is also  
available online at [http://  
www.nara.gov/fedreg](http://www.nara.gov/fedreg).

The text of laws is not  
published in the **Federal  
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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.access.gpo.gov/nara/  
index.html](http://www.access.gpo.gov/nara/index.html). Some laws may  
not yet be available.

### **H.R. 2084/P.L. 106-69**

Department of Transportation  
and Related Agencies  
Appropriations Act, 2000 (Oct.  
9, 1999; 113 Stat. 986)

### **S. 1606/P.L. 106-70**

To extend for 9 additional  
months the period for which  
chapter 12 of title 11, United  
States Code, is reenacted.  
(Oct. 9, 1999; 113 Stat. 1031)

### **S. 249/P.L. 106-71**

Missing, Exploited, and  
Runaway Children Protection  
Act (Oct. 12, 1999; 113 Stat.  
1032)

### **Last List October 8, 1999**

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